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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US00/02569  <b>(22) International Filing Date:</b> 1 February 2000 (01.02.00)  <b>(30) Priority Data:</b> 60/118,211 1 February 1999 (01.02.99) US 60/125,191 18 March 1999 (18.03.99) US  <b>(71) Applicant:</b> BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM [US/US]; 201 West 7th Street, Austin, TX 78701 (US).  <b>(72) Inventors:</b> HYODOH, Hideki; Kawachi, Tochigi (JP). KONYA, Andras; 550 N. Braeswood #256, Houston, TX 77096 (US). WRIGHT, Kenneth, C.; 1802 Haver, Houston, TX 77006-2414 (US).  <b>(74) Agent:</b> GARRETT, Mark, T.; Fulbright & Jaworski, Suite 2400, 600 Congress Avenue, Austin, TX 78701 (US).		<b>(81) Designated States:</b> AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>
<b>(54) Title:</b> WOVEN INTRAVASCULAR DEVICES AND METHODS FOR MAKING THE SAME AND APPARATUS FOR DELIVERY OF THE SAME  <b>(57) Abstract</b>  <p>Self-expandable, woven intravascular devices for use as stents (both straight and tapered), filters (both temporary and permanent) and occluders for insertion and implantation into a variety of anatomical structures. The devices may be formed from shape memory metals such as nitinol. The devices may also be formed from biodegradable materials. Delivery systems for the devices include two hollow tubes that operate coaxially. A device is secured to the tubes prior to the implantation and delivery of the device by securing one end of the device to the outside of the inner tube and by securing the other end of the device to the outside of the outer tube. The stents may be partially or completely covered by graft materials, but may also be bare. The devices may be formed from a single wire. The devices may be formed by either hand or machine weaving. The devices may be created by bending shape memory wires around tabs projecting from a template, and weaving the ends of the wires to create the body of the device such that the wires cross each other to form a plurality of angles, at least one of the angles being obtuse. The value of the obtuse angle may be increased by axially compressing the body.</p>		

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**APPLICATION FOR UNITED STATES LETTERS PATENT**

**for**

**WOVEN INTRAVASCULAR DEVICES AND METHODS FOR MAKING  
THE SAME AND APPARATUS FOR DELIVERY OF THE SAME**

## BACKGROUND OF THE INVENTION

The present application claims priority to U.S. Provisional Patent Application Serial No. 60/118,211 filed February 1, 1999 and U.S. Provisional Patent Application Serial No. 60/125,191 filed March 18, 1999. The entire texts of the above-referenced disclosures are specifically incorporated by reference herein without disclaimer.

### 1. Field of the Invention

The present invention relates generally to intravascular devices. More particularly, it concerns self-expandable woven intravascular devices for use as stents, occluders or filters, the methods of making the same, and the apparatus and methods for delivery of the same into a living creature.

### 2. Description of Related Art

Intravascular devices that serve as stents or filters constructed using a plain weave, such as the stent disclosed in U.S. Patent No. 4,655,771 to Wallsten (hereinafter, the WALLSTENT), have a propensity to show a high-degree of elongation axially with diameter reduction. This is especially significant, when the angle of the crossing wires is close to the largest possible. The closer that the angle between the wires is to 180°, the more the corresponding elongation of the stent is at a given percentage of decrease in diameter. Any discrepancy between the diameters of the stent and the vessel can result in a considerable elongation of the stent. Simultaneously, the woven type stent has the largest expansile force and hence the biggest resistance to outer compression when the angle between the crossing wires is close to 180°. In some applications, such as outer compression by a space occupying lesion, the increased radial force may be advantageous. The disadvantage of a propensity for elongation is that great care must be taken when delivering such a stent in a vessel or non-vascular tubular structure in order to properly position it.

A further disadvantage of intravascular devices formed using a plain weave, is that they are often incapable of maintaining their shape when bent. For example, when

1 such a stent is being delivered through a tortuous passageway with many turns, upon  
2 being bent, the weave of the stent tightens (e.g., the angle of the crossing wires  
3 approaches 180°). As a result of this tightening, the diameter of the stent increases and  
4 the length of the stent decreases. Consequently, the diameter of the stent may exceed the  
5 diameter of the vessel or structure through which it is traveling, impeding the delivery of  
6 the stent or causing the stent to lodge in the vessel. This problem may be due in part to  
7 the use of weave materials such as stainless steel, which exhibit poor shape memory.  
8 This problem may also be due to the free, unclosed wires used to form the stent. The free  
9 sharp ends can create potential complications by penetrating, or perforating the wall of  
10 the tubular structure where such a stent is placed. Further, steps that have been taken to  
11 eliminate the free, sharp ends, such as connection with U-shaped members using welding,  
12 glue or the like (Wallsten, 1987) are time-consuming and expensive. The delivery  
13 systems for such devices have also suffered from problems relating to the  
14 repositionability of the devices as they are delivered into position in the living creature.

15 In stenting long arterial segments, the contiguously decreasing diameter of the  
16 arterial system from the center to the periphery may pose problems. Woven stents with a  
17 uniform diameter will exert a substantial expansile force to the vessel wall along the  
18 tapered portion. Additionally, the stent may remain more elongated in the tapered  
19 portion. In a study where WALLSTENTs with a uniform diameter were used to bridge  
20 central venous obstruction in hemodialysis patients, it was found that the stents which  
21 were selected according to the size of the larger diameter central vein exerted  
22 considerably higher force to the wall of the smaller caliber subclavian vein (Vesely,  
23 1997). Simultaneously, the length of the stents in the smaller caliber vein was longer than  
24 expected.

25 In the prior art, most of the filter designs except for the Bird's Nest filter (Cook  
26 Inc., Bloomington, IN) have a conical shape and are anchored with multiple legs in the  
27 wall of the cava. The conical design is used because the main stream of the blood carries  
28 the thrombi from the lower part of the body through the center of the inferior vena cava.  
29 Therefore, all these devices are designed to have good filtration capacity at the center of

1 the cava. The situation is quite different after some thrombi have been successfully  
2 captured. The center of the cava will no longer be patent and as a result, the blood will be  
3 diverted from the center to the periphery of the cava. The aforementioned designs,  
4 however, are not capable of catching thrombi effectively at the periphery of the lumen so  
5 the patients will practically be unprotected against subsequent peripheral embolization  
6 (Xian, 1995; Jaeger, 1998). Further, most of filters tend to be tilted in the cava which can  
7 deter their thrombus-capturing efficacy. Additionally, except for the Simon nitinol filter  
8 (C.R. Bard, New Jersey, NJ) the aforementioned designs require a fairly large invasive  
9 delivery system of 10-F or larger.

10 The uniform caliber of cylindrical stents in the prior art used in the ureter, as well  
11 as the peristalsis arrested at the proximal end of the stent, has resulted in severe  
12 hyperlasia of the urothelium and eventually occlusion of the ureter.

13 Turning to occluders, percutaneous occlusion techniques have become  
14 indispensable tools in minimally invasive management of a wide range of pathological  
15 conditions. Use of permanent mechanical occlusion devices has been shown to be  
16 equivalent to that of surgical ligation. The Gianturco-Wallace stainless steel coil (Cook  
17 Inc., Bloomington, IN) has been the most widely used permanent, expandable  
18 intravascular occlusion device for transcatheter delivery (Gianturco *et al.*, 1975).

19 Percutaneous coil embolization has been shown to be advantageous over  
20 traditional surgical procedures in treatment of life threatening hemorrhage due to trauma  
21 or obstetric emergencies (Schwartz *et al.*, 1993; Teitelbaum *et al.*, 1993; Selby Jr., 1992;  
22 Levey *et al.*, 1991; Ben-Menachem *et al.*, 1991; Vedantham *et al.*, 1997). Furthermore,  
23 coils have been used alone or in combination with microvascular embolic agents for the  
24 treatment of vascular fistulas and malformations, tumors, and varices (Wallace *et al.*,  
25 1979; Hendrickx *et al.*, 1995; Furuse *et al.*, 1997; White *et al.*, 1996; Sagara *et al.*, 1998;  
26 Puneekar *et al.*, 1996). During the last few years, the transcatheter closure of the patent  
27 ductus arteriosus (PDA) with coils has become a frequently used technique (Hijazi and  
28 Geggel, 1994; Hijazi and Geggel, 1997).

1           Although coil type occlusion devices have shown at least a degree of utility, they  
2           have a number of drawbacks that could be significant in some applications. Intravascular  
3           stability of the coils has been shown to be highly dependent on proper matching of coil  
4           diameter with the diameter of the target vessel (Nancarrow *et al.*, 1987), and with the  
5           exception of small vessels, a single coil rarely results in a stable occlusive thrombus  
6           (Hijazi and Geggel, 1994). Moreover, a long vascular segment is often obliterated  
7           because of the frequent need for multiple coils and the coils often remain elongated  
8           within the vessel because their unconstrained diameter is larger than the vascular lumen.  
9           Furthermore, delayed recanalization rates of 37%-57% have been reported in humans  
10          within 1-3 months after initially successful coil embolization (Sagara *et al.*, 1998;  
11          O'Halpin *et al.*, 1984; Schild *et al.*, 1994).

12          These and other drawbacks have inspired modifications in the design and  
13          technique of coil embolization. Recently, detachable microcoils and macrocoils with  
14          controlled delivery have been designed to achieve a more compact conglomerate of the  
15          coil and to prevent migration by allowing optimal positioning of the coil before release  
16          (Zubillaga *et al.*, 1994; Guglielmi *et al.*, 1995; Marks *et al.*, 1994; Reidy and Qureshi,  
17          1996; Uzun *et al.*, 1996; Tometzki *et al.*, 1996; Dutton *et al.*, 1995). However, since  
18          optimal arrangement of the coil alone may not prevent migration in some cases, such as  
19          high flow conditions or venous placement, a coil anchoring system has been devised  
20          (Kónya *et al.*, 1998). Although an anchoring system may stabilize a coil conglomerate  
21          within the vasculature, significantly reducing or eliminating the possibility of coil  
22          migration, such a system may render the coil non-repositionable.

23          Several different non-coil devices have been designed to achieve a more stable,  
24          limited size plug with higher hemostatic efficiency particularly for transcatheter closure  
25          of larger vessels (Schmitz-Rode *et al.*, 1993; Kato *et al.*, 1997; Kónya *et al.*, 1999) and  
26          PDAs (Pozza *et al.*, 1995; Magal *et al.*, 1989; Grifka *et al.*, 1996). Recently, initial  
27          clinical experiences with a new self-expanding nitinol-mesh PDA occluder have been  
28          reported (Sharafuddin *et al.*, 1996; Masura *et al.*, 1998). A similar self-expanding,  
29          repositionable quadruple-disc device constructed of a braided nitinol mesh and polyester

1 fibers has been reported to be superior to standard Gianturco coils in experimental  
2 occlusion of mid-size arteries (Sharaffuddin *et al.*, 1996).

3 Although such non-coil devices may be repositionable, they too exhibit  
4 drawbacks. For instance, the quadruple-disc device is several centimeters long in an  
5 elongated fashion, making difficult to keep the superselective position of the catheter tip  
6 during deployment. The multiple rigid connections between the layers and the relative  
7 long and rigid connection between the occluder and the delivery cable further increase  
8 this drawback. Although the nitinol mesh-PDA occluder has demonstrated utility, its  
9 proper placement requires a proper match both in size and shape between the occluder  
10 and the lesion to be occluded. The type and quality of the connection between the  
11 occluder and the delivery cable is the same as in the quadruple-disc design. A common  
12 disadvantage of both designs is that they lack guidewire compatibility. As a result, a  
13 delivery catheter must often be navigated to the site of occlusion first before an occluder  
14 may be loaded into the catheter and delivered through it. Another relative disadvantage  
15 of both devices is their cost of manufacturing.

16 Percutaneous catheter technique for permanent closure of isolated persistently  
17 patent ductus arteriosus (PDA) is now a treatment of choice among doctors, obviating  
18 open surgery. The configuration of the PDA varies considerably. A majority of PDAs  
19 tend to have a funnel or conical shape due to ductal smooth muscle constriction at the  
20 pulmonary artery insertion, although narrowings in the middle or aortic ends can be  
21 observed (Krichenko, 1989). That is the reason why not only the size, but also the  
22 configuration, of the lesion plays a significant role in selecting an appropriate occluding  
23 device. Except from the small caliber lesions (with a maximum diameter of 2.5 mm or  
24 3.3 mm, respectively), where some authors have achieved successful closure of the PDA  
25 with Gianturco coils (Cambier, 1992; Lloyd, 1993; Sommer, 1994), Rashkind's "double  
26 umbrella" occluder is the most often used device for this purpose (Rashkind, 1987;  
27 Hosking, 1991; Latson, 1991; Wessel, 1988; Report of the European Registry, 1992). It  
28 is available in two sizes (with a diameter of 12 mm and 17 mm) which require a 8-F and  
29 11-F delivery system, respectively.

1 In the majority of cases, the deployment of the traditional PDA device is  
2 performed from a femoral vein access (Report of the European Registry, 1992). Because  
3 of the size of the delivery sheath, such a device is not suitable for the treatment of patients  
4 with a body weight of less than 8 kg. Using even a larger umbrella, this procedure is not  
5 recommended for the treatment of the lesions with a diameter of 8 mm or above (Latson,  
6 1991). About 80% of unselected patients with isolated PDA are candidates for the  
7 Rashkind device using the aforementioned criteria (Latson, 1991). With the Rashkind  
8 device, the proportion of patients with residual flow through the lesion fell from 76%  
9 immediately after implantation to 47% by the day after implantation and to 17% by a year  
10 after implantation (Report of the European Registry, 1992). According to some authors  
11 the residual flow carries a potential risk of infective endocarditis and should be avoided if  
12 possible. Its abolishment can be achieved by implantation of another device or surgery.

13 One of the main drawbacks of the Rashkind umbrella is that it is not suitable for  
14 occlusion of all types of PDA. Preferably, it is used to occlude short PDAs with  
15 relatively wide end-openings. Its two discs cover both the pulmonary and the aortic  
16 opening of the PDA. Longer PDA may hinder the discs to be positioned in the proper  
17 way, that is, parallel to each other, thereby deteriorating its self-anchoring. Another  
18 disadvantage of the umbrella is that the occluding capacity of the design depends  
19 exclusively on the thrombogenicity of the porous Dacron material, frequently resulting in  
20 partial and lengthy occlusion.

21 For the majority of patients with urinary leakage and/or fistulas (mainly due to  
22 tumor propagation to their ureters), the diversion of urine is currently performed by a  
23 percutaneous transrenal approach together with ureteral occlusion. Formerly, detachable  
24 and non detachable balloons were used for this purpose, but they did not cause  
25 satisfactory ureteral occlusion. Migration as well as deflation of the balloons occurred  
26 relatively frequently (Gunter, 1984; Papanicolau, 1985) leading to recurrence of the urine  
27 leakage. A silicone ureteral occluder was developed and used with only limited success  
28 because of device migration (Sanchez, 1988). This resulted in repositioning and  
29 consequent incomplete ureteral occlusion. It appears that the best results have been

1 accomplished with Gianturco coils and Gelfoam embolization (Gaylord, 1989; Bing,  
2 1992 a; Farrel, 1996). Even with multiple coil placements, together with Gelfoam plugs,  
3 the ureteral occlusion may sometimes be achieved for only weeks or months, and was  
4 attributed mostly to the induced urothelial hyperplasia (Bing, 1992 b). Coil migration  
5 was frequently encountered in these studies. The lack of appropriate self-anchoring  
6 results in coil migration which eventually deteriorates the occlusive effect.

7 Problems pointed out in the foregoing are not intended to be exhaustive but rather  
8 are among many that tend to impair the effectiveness of previously known stents,  
9 occluders and filters. Other noteworthy problems may also exist; however, those  
10 presented above should be sufficient to demonstrate that previous techniques appearing in  
11 the art have not been altogether satisfactory, particularly in providing flexible, self-  
12 expanding, repositionable stents, occluders and filters.

### 13 SUMMARY OF THE INVENTION

14 The present invention overcomes the problems inherent in the prior art by  
15 providing a self-expandable, repositionable device for use as a stent, an occluder, or a  
16 filter which may be formed using a plain weave, and may have closed structures at both  
17 its ends.

18 In one respect, the invention is a device that includes, but is not limited to, a  
19 plurality of shape memory wires woven together to form a body suitable for implantation  
20 into an anatomical structure. The body has first and second ends. The shape memory  
21 wires cross each other to form a plurality of angles, at least one of the angles being  
22 obtuse. Both ends of at least one shape memory wire are located proximate one end of  
23 the body. The value of the obtuse angle is increased when the body is axially  
24 compressed.

25 The shape memory wires may be made of nitinol. The shape memory wires may  
26 be made of FePt, FePd or FeNiCoTi. The shape memory wires may be made of FeNiC,  
27 FeMnSi or FeMnSiCrNi. The shape memory wires may each have a diameter ranging in  
28 size from about 0.006 inches to about 0.012 inches. The plurality of shape memory wires



1 may include at least 6 shape memory wires. The body may have a tubular shape with a  
2 substantially uniform diameter. The body may have a tapered shape with a diameter that  
3 decreases from one end of the body to the other end of the body. The body may have a  
4 generally hourglass shape. As used herein, "a generally hourglass" shape is a shape that  
5 resembles a body having two ends that are larger in terms of cross-sectional area than a  
6 mid-portion located therebetween. Such shapes include those resembling traditional  
7 hourglasses or dumbbells, for example. The body may be woven by hand. The body may  
8 be woven by a machine, such as a braiding machine.

9 The device may also include, but is not limited to, a graft material attached to the  
10 body. The graft material may be made from woven polyester. The graft material may be  
11 made from Dacron. The graft material may be made from polyurethane. The graft  
12 material may be made from PTFE. The graft material may partially cover the body. As  
13 used herein, a graft material that "partially covers" a body is attached to the body such  
14 that a portion of the wire or wires forming the body are left bare or exposed. As a result  
15 of only partially covering a body, blood or other bodily fluids may flow through the bare  
16 portion of the body relatively unimpeded by the graft material.

17 The device may also include, but is not limited to, a first tube that is configured to  
18 accept a guide wire and a second tube that is configured to fit over the first tube. Prior to  
19 delivering the body into an anatomical structure, the second tube is placed over the first  
20 tube, one end of the body is secured to the first tube and the other end of the body is  
21 secured to the second tube.

22 In another respect, the invention is a device that includes, but is not limited to, a  
23 body suitable for implantation into an anatomical structure. The body has a first end, a  
24 second end and is defined by at least  $n$  shape memory wires, wherein  $n$  is greater than  
25 one. The  $n$  shape memory wires are arranged such that the body includes a first portion.  
26 The first portion includes a first woven portion and at least one strut. The shape memory  
27 wires of the first woven portion cross each other to form a plurality of angles, at least one  
28 of the angles being obtuse. Both ends of at least one shape memory wire are located

1 proximate one end of the body. The value of the obtuse angle is increased when the body  
2 is axially compressed.

3 The shape memory wires may be made from nitinol. The shape memory wires  
4 may be made from FePt, FePd or FeNiCoTi. The shape memory wires may be made of  
5 FeNiC, FeMnSi or FeMnSiCrNi. The first portion may include a first woven portion  
6 separated from a second woven portion by multiple first struts.

7 The body may also include, but is not limited to, a second portion located adjacent  
8 to the first portion. The second portion includes a second woven portion. The second  
9 portion has  $n + x$  shape memory wires, and  $x$  is at least one. The first portion may have a  
10 generally domed shape. The first woven portion may have a generally domed shape and  
11 the multiple first struts may be bent slightly so as to increase the self-anchoring capability  
12 of the body in an anatomical structure. The first portion may also include a third woven  
13 portion separated from the second woven portion by multiple second struts. The first and  
14 third woven portions may have generally domed shapes.

15 The device may also include, but is not limited to, a graft material attached to the  
16 body. The graft material comprises may be made from woven polyester. The graft  
17 material may be made from Dacron. The graft material may be made from polyurethane.  
18 The graft material may be made from PTFE. The graft material may partially cover the  
19 body.

20 The device may also include, but is not limited to, a first tube that is configured to  
21 accept a guide wire and a second tube that is configured to fit over the first tube. Prior to  
22 delivering the body into an anatomical structure, the second tube is placed over the first  
23 tube, one end of the body is secured to the first tube and the other end of the body is  
24 secured to the second tube.

25 In another respect, the invention is a device that includes, but is not limited to, a  
26 plurality of biodegradable filaments woven together to form a self-expanding body  
27 suitable for implantation into an anatomical structure. The self-expanding body has a  
28 first end and a second end. The biodegradable filaments cross each other to form a

1 plurality of angles, at least one which is obtuse. The value of the obtuse angle is  
2 increased when the body is axially compressed.

3 The biodegradable filaments may be made from polyglycolic acid. The  
4 biodegradable filaments may be made from poly-L-lactic acid. The biodegradable  
5 filaments may be made from a polyorthoester. The biodegradable filaments may be made  
6 from a polyanhydride. The biodegradable filaments may be made from a  
7 polyiminocarbonate. The biodegradable filaments may be made from an inorganic  
8 calcium phosphate. The biodegradable filaments may include about 0.05 to 0.25 percent  
9 by weight of calcium oxide, calcium hydroxide, calcium carbonate, calcium phosphate,  
10 magnesium oxide, magnesium hydroxide, magnesium carbonate, magnesium phosphate,  
11 sodium phosphate or potassium sulfate. The biodegradable filaments may be made from  
12 a polymer having about 15 to about 30 mole percent glycolide. At least one of the  
13 biodegradable filaments may be made from paclitaxel, docetaxel or heparin. Both ends of  
14 at least one biodegradable filament may be located proximate the first end of the self-  
15 expanding body. Each end of the self-expanding body may include at least one closed  
16 structure.

17 The device may also include, but is not limited to, at least one shape memory wire  
18 secured to the self-expanding body. Both ends of the one shape memory wire may be  
19 located proximate one end of the self-expanding body.

20 In another respect, the invention is a method of creating a body suitable for  
21 implantation into an anatomical structure. The body has two end ends. The method  
22 includes, but is not limited to, bending the shape memory wires in a plurality of shape  
23 memory wires to create bent portions in the shape memory wires. The bent portions are  
24 arranged to define one end of the body. Each shape memory wire has two ends. The  
25 method also includes, but is not limited to, weaving the ends of the shape memory wires  
26 to create the body such that the shape memory wires cross each other to form a plurality  
27 of angles, at least one of the angles being obtuse. The value of the obtuse angle is  
28 increased when the body is axially compressed.

1           The bent portions may be bends or loops. The shape memory wires may be made  
2           from nitinol. The shape memory wires may be made of FePt, FePd or FeNiCoTi. The  
3           shape memory wires may be made of FeNiC, FeMnSi or FeMnSiCrNi. The shape  
4           memory wires may each have a diameter ranging in size from about 0.006 inches to about  
5           0.012 inches. The plurality of shape memory wires may include at least 6 shape memory  
6           wires. The body may have a tubular shape with a substantially uniform diameter. The  
7           body may have a tapered shape with a diameter that decreases from one end of the body  
8           to the other end of the body. The body may have a generally hourglass shape. The body  
9           may be woven by hand. The body may be woven by a machine, such as a braiding  
10          machine.

11          In another respect, the invention is a method of creating a body suitable for  
12          implantation into an anatomical structure. The body has two ends. The method includes,  
13          but is not limited to, providing a weaving system that includes a template having first  
14          template projections. The method also includes, but is not limited to, bending shape  
15          memory wires around the first template projections to create bent portions in the shape  
16          memory wires. The bent portions are arranged to define one end of the body. Each shape  
17          memory wire has two ends. The method also includes, but is not limited to, weaving the  
18          ends of the shape memory wires around the template to create the body such that the  
19          shape memory wires cross each other to form a plurality of angles, at least one of the  
20          angles being obtuse. The value of the obtuse angle is increased when the body is axially  
21          compressed.

22          The first template projections may be tabs. The first template projections may be  
23          pins. The pins may be attached to a ring engaged with the template. The weaving system  
24          may also include, but is not limited to, a first weaving plate configured to rotate in a first  
25          direction during the weaving. The weaving system may also include, but is not limited to,  
26          first bobbins arranged on the first weaving plate, and one end of each shape memory wire  
27          is attached to each first bobbin prior to the weaving. The weaving system may also  
28          include, but is not limited to, a second weaving plate configured to rotate in a second  
29          direction during the weaving, and the second weaving plate is spaced apart from the first

1 weaving plate. The weaving system may also include, but is not limited to, second  
2 bobbins arranged on the second weaving plate, and one end of each shape memory wire is  
3 attached to each second bobbin prior to the weaving. The method may also include, but  
4 is not limited to, securing the shape memory wires to the template. The method may also  
5 include, but is not limited to, forming closed structures with the ends of the shape  
6 memory wires. The closed structures may be arranged to define the other end of the  
7 body. The method may also include, but is not limited to, heating the body and the  
8 template.

9 In another respect, the invention is a device for delivering an axially and radially  
10 expandable woven body having two ends into an anatomical structure. The device  
11 includes, but is not limited to, a first tube configured to accept a guide wire, and a second  
12 tube configured to fit over the first tube. When the tubes are used for delivering the  
13 axially and radially expandable woven body, one end of the axially and radially  
14 expandable woven body is secured to the outside of the first tube and the other end of the  
15 axially and radially expandable woven body is secured to the outside of the second tube.

16 The first tube may be made from NYLON or TEFLON. The second tube may be  
17 made from NYLON or TEFLON. The device may also include, but is not limited to, a  
18 guide wire configured to be placed within the first tube. The outer diameter of the first  
19 tube may range in size from 3 French to 7 French. The outer diameter of the second tube  
20 may range in size from 5 French to 9 French. The device may also include, but is not  
21 limited to, a push-button release/lock mechanism configured to secure the first tube to the  
22 second tube. The device may also include, but is not limited to, an end fitting having a  
23 side arm. The end fitting is configured to be secured to the first tube. The first tube may  
24 be provided with at least one pair of first tube holes through which a first securing wire  
25 may be threaded. The pair of first tube holes may be positioned proximate one end of the  
26 first tube. The second tube may be provided with at least one pair of second tube holes  
27 through which a second securing wire may be threaded. The pair of second tube holes  
28 may be positioned proximate one end of the second tube.

1           In another respect, the invention is a device for delivering an axially and radially  
2 expandable woven body having two ends into an anatomical structure. The device  
3 includes, but is not limited to, a first tube configured to accept a guide wire. The first  
4 tube has at least one pair of first tube holes that are positioned proximate one end of the  
5 first tube. The device also includes, but is not limited to, a second tube configured to fit  
6 over the first tube. The second tube has at least one pair of second tube holes that are  
7 positioned proximate one end of the second tube. The device also includes, but is not  
8 limited to, a first securing wire configured to be threaded through the pair of first tube  
9 holes. The device also includes, but is not limited to, a second securing wire configured  
10 to be threaded through the pair of second tube holes. When the tubes are used for  
11 delivering the axially and radially expandable woven body, one end of the axially and  
12 radially expandable woven body is secured to the outside of the first tube with the first  
13 securing wire and the other end of the axially and radially expandable woven body is  
14 secured to the outside of the second tube with the second securing wire.

15           In another respect, the invention is an occluding system that includes, but is not  
16 limited to, a plurality of shape memory wires woven together to form a body useful for  
17 occluding an anatomical structure. The body has first and second ends. Both ends of at  
18 least one shape memory wire are located proximate one end of the body. The shape  
19 memory wires cross each other to form a plurality of angles, at least one of the angles  
20 being obtuse. The value of the obtuse angle is increased when the body is axially  
21 compressed.

22           The shape memory wires may be made from nitinol. The occluding system may  
23 also include, but is not limited to, an occluding agent enclosed within the body. The  
24 occluding agent may include one or more threads of polyester. The occluding agent may  
25 also include, but is not limited to, one or more threads of DACRON. The occluding  
26 system may also include a jacket coupled to the body. The jacket may be made from  
27 silicone. The jacket may be made from polyurethane. The occluding system may also  
28 include, but is not limited to, a first tube configured to accept a guide wire, and a second  
29 tube configured to fit over the first tube. Prior to delivering the body into an anatomical

1 structure, one end of the body is secured to the outside of the first tube and the other end  
2 of the body is secured to the outside of the second tube.

3 In another respect, the invention is a device that includes, but is not limited to, a  
4 body suitable for implantation into an anatomical structure. The body has an axis, a first  
5 end and a second end. The body is made from a shape memory wire that has a first  
6 segment and a second segment. The segments are separated by a bend in the shape  
7 memory wire that is located proximate one end of the body. The first segment extends  
8 helically in a first direction around the axis toward the other end of the body. The second  
9 segment extends helically in a second direction around the axis toward the other end of  
10 the body. The first and second segments cross each other in a plurality of locations.

11 The first segment may be positioned farther from the axis than the second segment  
12 at at least one location. The first segment may be positioned farther from the axis than  
13 the second segment at each location. The shape memory wire may be made from nitinol.  
14 The device may also include a first tube configured to accept a guide wire, and a second  
15 tube configured to fit over the first tube. Prior to delivering the body into an anatomical  
16 structure, one end of the body is secured to the outside of the first tube and the other end  
17 of the body is secured to the outside of the second tube.

18 In another respect, the invention is a device that includes, but is not limited to, a  
19 body suitable for implantation into an anatomical structure. The body has a first end and  
20 a second end. The body is formed from a shape memory wire that has a first segment and  
21 a second segment. The segments are separated by a bend in the wire that is located  
22 proximate one end of the body. The first segment and second segments are arranged to  
23 form loops and twisted segments such that at least two contiguous loops are separated  
24 from another loop by a twisted segment. The definition of "contiguous" is set forth  
25 below with reference to the figures herein for the sake of clarity.

26 At least three contiguous loops may be separated from another loop by a twisted  
27 segment. At least four contiguous loops may be separated from another loop by a twisted  
28 segment. At least two contiguous loops may be separated from two other contiguous

1 loops by a twisted segment. The shape memory wire may be made from nitinol. The  
2 device may also include, but is not limited to, a first tube configured to accept a guide  
3 wire, and a second tube configured to fit over the first tube. Prior to delivering the body  
4 into an anatomical structure, one end of the body is secured to the outside of the first tube  
5 and the other end of the body is secured to the outside of the second tube.

6 In another respect, the invention is a device that includes a body suitable for  
7 implantation into an anatomical structure. The body has, but is not limited to, two ends  
8 and is formed from a shape memory wire that has a first segment and a second segment.  
9 The segments are separated by a bend in the wire that is located proximate one end of the  
10 body. The segments are positioned adjacent to each other in loop-defining locations. The  
11 segments also extend between the loop-defining locations in spaced relation to each other  
12 so as form at least two loops. At least one of the at least two loops has a compressed  
13 shape. The definition of a "compressed" shape is set forth below with reference to the  
14 figures herein for the sake of clarity.

15 The shape memory wire may be made from nitinol. The segments may be secured  
16 together using welds at the loop-defining locations. The segments may be secured  
17 together with collars at the loop-defining locations. The body may also include, but is not  
18 limited to, at least one coil placed over at least a portion of one of the segments, and, as a  
19 result, the body may be used as an occluder. The body may also include at least one fiber  
20 attached to the coil. The device may also include, but is not limited to, a first tube  
21 configured to accept a guide wire, and a second tube configured to fit over the first tube.  
22 Prior to delivering the body into an anatomical structure, one end of the body is secured  
23 to the outside of the first tube and the other end of the body is secured to the outside of  
24 the second tube.

25 The present invention also provides a delivery system that may secure both the  
26 proximal and distal ends of the stent, occluder or filter. Advantageously, this delivery  
27 system allows the stent, occluder or filter to be easily repositioned as it is being delivered  
28 into place. As a result, the stent, occluder or filter may be more precisely positioned  
29 within the living creature.



1           One advantage of the present invention is the unique fixation method of the  
2 tapered stent. The tapered shape of the stent allows the stent to be fixed in a tapered  
3 vessel or tubular structure with less radial or expansile force than a straight stent might  
4 exhibit, thus potentially resulting in a less hyperplastic intimal reaction.

5           The straight stent of the present invention exhibits a high expansile force and thus  
6 a large capability of withstanding outer compression. This may be especially  
7 advantageous in tumorous stenoses, or fibrous strictures (including radiation-induced  
8 stenoses) where stents with inadequate expansile forces can be easily compressed and/or  
9 are incapable of assuming their nominal shape and diameter. In some cases, even the  
10 stenoses of arteriosclerotic origin can be so calcified (*e.g.*, iliac or renal artery stenoses)  
11 that extra radial force is required from the stent to hold the patency of the vessel.  
12 Furthermore, the woven intravascular devices of the present invention are also able to  
13 return to their original, unconstrained shape after being bent, even maximally.

14           Advantageously, the stents, occluders and filters of the present invention do not  
15 possess free, sharp wire ends. Thus, many potential complications are eliminated  
16 (Prahlow, 1997). Additionally, the tight mesh of the stents of the present invention  
17 coupled with the use of nitinol wires, for example, makes them easy to monitor under  
18 fluoroscopy.

19           The present invention also includes a group of self-expanding, self-centering cava  
20 filters woven from materials as described above such that a coherent element is formed  
21 that without the use of a joint or attachment between the portions of the filters. The cava  
22 filters of the present invention provide increased filtrating efficiency not only at the center  
23 but also at the periphery of the cava. Additionally, the hourglass filter of the present  
24 invention utilizes multiple filtration levels. The cava filters of the present invention are  
25 able to self-center due to the symmetrical nature of their design and their potentially  
26 flared base.

27           The cava filters of the present invention may utilize a relatively small, 7 French  
28 delivery catheter or sheath. Additionally, the superb flexibility of the cava filters makes it

1 possible to deliver them *via* any of the possible access sites of the human body (femoral;  
2 jugular, antecubital veins).

3 The present invention also includes a bi-iliac filter ("BI filter") that is a low-  
4 profile, self-expanding, flexible, temporary filter which may be woven from a number of  
5 superelastic or shape memory alloys. The BI filter is a type of temporary filter that can be  
6 deployed from either femoral vein, and it can filtrate the blood at the iliac veins/inferior  
7 cava junction. The BI filter of the present invention typically works at a low level of  
8 venous circulation. Advantageously, the BI filter simultaneously filters all the blood  
9 coming from both iliac veins, achieving almost 100% filtration. Further, the use of the BI  
10 filter is particularly beneficial in perioperative and posttraumatic cases.

11 The inverse U-shape of the BI filter together with the expansile force of the  
12 tubular weave ensures firm position along the iliac/cava junction. A further advantage of  
13 the present invention is that the BI filter may utilize a relatively small, 7 French delivery  
14 catheter or sheath. Further, due to the flexibility of the mesh of the BI filter, the delivery  
15 system thereof may be advanced from ipsi- to contralateral iliac vein. As with the cava  
16 filters, the BI filter may possess a non-ferromagnetic character making it MRI compatible.

17 The BI filter is suitable for temporary filtration. The BI filter allows for removal  
18 of the entrapped thrombi safely and successfully before removal of the filter. Using an  
19 adequately sized sheath, the small thrombus fragments entrapped within the mesh could  
20 also be removed together with the filter.

21 The stents of the present invention can be advantageously covered with materials  
22 such as silicone, polyurethane, and/or an anticancer coating agent that allow the stents to  
23 reduce the possibility of restenosis after delivery, and which also allow the stents to be  
24 used in stenting malignant stenoses, for example. The filters of the present invention may  
25 also be covered with anticoagulant coating agents.

26 Ureter strictures/compression/occlusion may be stented with these uncovered  
27 and/or covered stents; in particular, the use of a long tapered stent may advantageously

1 match the special conditions posed by the different caliber and distensibility of the  
2 different segments of the ureter as well as the constant peristalsis.

3 The stents of the present invention can also be used in some non-vascular  
4 applications including biliary tree and tracheo-bronchial system if the lesion does not  
5 require a bifurcated stent.

6 The stents, occluders and filters of the present invention may be used in many  
7 different applications. They provide the advantages of superb flexibility,  
8 repositionability/removability, and precise positionability.

### 9 BRIEF DESCRIPTION OF THE DRAWINGS

10 The following drawings form part of the present specification and are included to  
11 further demonstrate certain aspects of the present invention. The invention may be better  
12 understood by reference to one or more of these drawings in combination with the  
13 description of illustrative embodiments presented herein.

14 **FIG. 1A** is a perspective view of a stent according to one embodiment of the  
15 present invention.

16 **FIG. 1B** is a front view of a stent end defined by bends according to one  
17 embodiment of the present invention.

18 **FIG. 1C** is a perspective view of one wire of a stent according to one embodiment  
19 of the present invention.

20 **FIG. 2** is a side view of the arrangement of wires in a plain weave according to  
21 one embodiment of the present invention.

22 **FIG. 3** is a perspective view of a delivery system according to one embodiment of  
23 the present invention.

24 **FIG. 4** is a side view of a delivery system according to one embodiment of the  
25 present invention.

1           **FIGS. 5A-E** sequentially illustrative steps in a delivery method according to one  
2           embodiment of the present invention.

3           **FIG. 6** is a front view of a conical filter having bends or loops in the proximal  
4           (rear) end thereof according to one embodiment of the present invention.

5           **FIG. 7** is a front view of a conical filter having bends or loops in the distal (front)  
6           end thereof according to one embodiment of the present invention.

7           **FIG. 8** is a front view of a dome filter having bends or loops in the distal end  
8           thereof according to one embodiment of the present invention.

9           **FIG. 9** is a front view of an hourglass filter according to one embodiment of the  
10          present invention.

11          **FIG. 10** is a front view of an hourglass filter according to one embodiment of the  
12          present invention placed in the Inferior Vena Cava.

13          **FIG. 11** is a front view of a bi-iliac filter according to one embodiment of the  
14          present invention placed in the iliac veins.

15          **FIG. 12** is a front view of a bi-iliac filter having a retrieval loop according to one  
16          embodiment of the present invention placed in the iliac veins.

17          **FIG. 13** is a front view of a bi-iliac filter having a retrieval loop and a stabilizing  
18          wire according to one embodiment of the present invention placed in the iliac veins.

19          **FIG. 14** is a perspective view of a tapered stent according to one embodiment  
20          of the present invention.

21          **FIG. 15** is a perspective view of a single wire embodiment filter according to one  
22          embodiment of the present invention.

23          **FIGS. 16-24** show stages in a hand weaving method according to one  
24          embodiment of the present invention.

1           **FIG. 25** is a front view of the proximal portion of a delivery system according to  
2 one embodiment of the present invention.

3           **FIG. 26** is a front view of a delivery system for a temporary filter according to  
4 one embodiment of the present invention.

5           **FIGS. 27A and B** illustrate stages in the removal of a filter from a vessel  
6 according to one embodiment of the present invention.

7           **FIG. 28** is a front view of a conical filter in a fully stretched position according to  
8 one embodiment of the present invention.

9           **FIG. 29** is a projected cross section of an hourglass filters taken across the middle  
10 portion of the filter according to one embodiment of the present invention.

11           **FIG. 30A** is a front view of two wires coupled together for use in a hand weaving  
12 method according to one embodiment of the present invention.

13           **FIG. 30B** is a perspective view of the placement of two wires each coupled to a  
14 pin for use in a hand weaving method according to one embodiment of the present  
15 invention.

16           **FIG. 31** is a perspective view of a biodegradable stent with a reinforcing wire  
17 according to one embodiment of the present invention.

18           **FIG. 32** is a perspective view of a biodegradable stent with a reinforcing wire  
19 according to a second embodiment of the present invention.

20           **FIGS. 33A-G** are front views of various configurations of an occluder according  
21 to the present invention.

22           **FIG. 34** is a front view of an occluder having a jacket according to one  
23 embodiment of the present invention.

1           **FIG. 35** is a front view of an occluder having clips according to one embodiment  
2 of the present invention.

3           **FIG. 36** is a front view of an aneurysm being treated by transcatheter  
4 embolization according to one embodiment of the present invention.

5           **FIG. 37** is perspective view of a template with longitudinal tabs around which  
6 wires are bent according to one embodiment of the present invention.

7           **FIG. 38A** is an enlarged perspective view of the longitudinal tab and bent wire  
8 depicted in **FIG. 37** according to one embodiment of the present invention.

9           **FIG. 38B** is an enlarged perspective view of a longitudinal tab depicted in **FIG.**  
10 **37** around which a wire is bent to form a loop according to one embodiment of the  
11 present invention.

12           **FIG. 39** is a perspective view of a wire bent around a longitudinal tab and  
13 wrapped around a pair of bobbins according to one embodiment of the present invention.

14           **FIG. 40** is a top view of inner and outer weaving plates provided with bobbins  
15 according to one embodiment of the present invention.

16           **FIG. 41** is a perspective view depicting an upper weaving plate provided with  
17 bobbins and wires, a partial cross-sectional view of a lower weaving plate provided with  
18 bobbins and wires, and a partial cross-sectional view of a template around which both  
19 plates are arranged according to one embodiment of the present invention.

20           **FIG. 42A** is a top view of upper and lower weaving plates provided with bobbins  
21 and wires and arranged around a template, and illustrates the first crossing of the wires  
22 according to one embodiment of the present invention.

23           **FIG. 42B** is a front view of a small caliber loop formed by bending a wire  
24 according to one embodiment of the present invention.

1           **FIG. 43A** is a top view of upper and lower weaving plates provided with bobbins  
2           and wires and arranged around a template, and illustrates the first crossing of the wires  
3           according to another embodiment of the present invention.

4           **FIG. 43B** is a front view of a bend formed by bending a wire according to one  
5           embodiment of the present invention.

6           **FIG. 44** is a perspective view of upper and lower weaving plates provided with  
7           bobbins and arranged around a template such that the surfaces of the weaving plates from  
8           which the bobbin rods extend face each other according to one embodiment of the present  
9           invention.

10          **FIG. 45** is a perspective view of upper and lower weaving plates provided with  
11          bobbins and wires and arranged around a template such that the surfaces of the weaving  
12          plates from which the bobbin rods extend face each other according to one embodiment  
13          of the present invention.

14          **FIG. 46A** is a perspective, partial cross-sectional view of a tool for twisting the  
15          wire ends of a woven body according to one embodiment of the present invention.

16          **FIG. 46B** is a cross-sectional view of the jaws and outer housing of the tool  
17          illustrated in **FIG. 46A**.

18          **FIG. 47A** is a perspective view of a body woven around a template having  
19          longitudinal and transverse tabs according to one embodiment of the present invention.

20          **FIG. 47B** is an enlarged perspective view of one of the transverse tabs and twisted  
21          wire ends depicted in **FIG. 47A** according to one embodiment of the present invention.

22          **FIG. 48** is a perspective view of a template around which a ring having finish pins  
23          has been threadably engaged according to one embodiment of the present invention.

24          **FIG. 49** is a perspective view of a template having finish holes through which  
25          finish pins may be placed according to one embodiment of the present invention.

1           **FIG. 50A** is a front view of a stent formed from a single wire according to one  
2           embodiment of the present invention.

3           **FIG. 50B** is a front view of a stent formed from a single wire according to a  
4           second embodiment of the present invention.

5           **FIG. 50C** is a front view of a stent formed from a single wire according to a third  
6           embodiment of the present invention.

7           **FIG. 50D** is a perspective view of the stent depicted in **FIG. 50B** positioned on a  
8           template according to one embodiment of the present invention.

9           **FIG. 51** is a perspective view of a barbless stent filter according to one  
10          embodiment of the present invention.

11          **FIG. 52** is a perspective view of a barbless stent filter having bent longitudinal  
12          segments according to one embodiment of the present invention.

13          **FIG. 53** is a perspective view of a barbless stent filter having two filtrating levels  
14          according to one embodiment of the present invention.

15          **FIG. 54** is a front view of two stents placed in side-by-side relationship with each  
16          other in the aorta according to one embodiment of the present invention.

17          **FIG. 55** is a perspective view of two partially-covered stents placed in side-by-  
18          side relationship with each other in the aorta according to one embodiment of the present  
19          invention.

20          **FIG. 56** is a perspective view of a stent having struts placed in side-by-side  
21          relationship with another stent in the aorta according to one embodiment of the present  
22          invention.

23          **FIGS. 57A** is a front view of an occluder formed from a single wire around a  
24          template according to one embodiment of the present invention.



1           **FIGS. 57B** is a perspective view of an occluder formed from a single wire that  
2 includes collars placed around the wire segments at loop-defining locations according to  
3 one embodiment of the present invention.

4           **FIGS. 57C** is a top view of an occluder formed from a single wire that has coil  
5 pieces placed over portions of the wire segments located between collars according to one  
6 embodiment of the present invention.

7           **FIGS. 57D** is a top view of an occluder formed from a single wire that has coil  
8 pieces placed over portions of the wire segments located between collars and also has  
9 thrombogenic filaments attached to the coil pieces according to one embodiment of the  
10 present invention.

11           **FIGS. 58A-D** show stages in the delivery of one stent of a pair of stents in the  
12 aorto-renal junction according to one embodiment of the present invention.

13           **FIG. 59** is a front view of a barb (of a filter) that is penetrating a vessel wall  
14 according to one embodiment of the present invention.

15           **FIG. 60** is a perspective view of a single wire embodiment filter according to  
16 another embodiment of the present invention.

17           **FIG. 61** is a front view of upper and lower weaving plates supported by a weaving  
18 plate supporter according to one embodiment of the present invention.

## 19           **DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS**

### 20           **1. Stents**

#### 21                   *Straight Stents*

22           With reference to the illustrative embodiment shown in **FIG. 1A**, there is shown a  
23 stent for insertion and delivery into an anatomical structure. The stent includes a plurality  
24 of wires 5 which may be arranged in a plain weave so as to define an elastically  
25 deformable body 10. As used herein, "elastically deformable" means that the

1 deformation of such a body is non-permanent and an original or initial shape may be  
2 substantially recovered, or regained, upon the release of a force (which may be  
3 mechanical, electromagnetic, or any other type of force). As used herein, "substantially  
4 recovered" means that recovery need not be such that the exact, original shape be  
5 regained. Rather, it means that some degree of plastic deformation may occur. In other  
6 words, recovery need not be total. Such elastic deformability may be achieved by  
7 utilizing the superelastic properties of suitable shape memory wires, which are discussed  
8 below.

9 U.S. Patent No. 4,655,771 to Wallsten (1987), which is hereby expressly  
10 incorporated by reference, displays the manner in which wires cross each other using  
11 plain weave as shown in FIG. 1a therein. FIG. 2 also illustrates the manner in which the  
12 wires 5 of the present intravascular devices may be arranged utilizing a plain weave.

13 Body 10 is both radially and axially expandable. Body 10 includes front or distal  
14 end 12 and rear or proximal end 2. As shown in FIG. 1A, end 12 has a plurality of closed  
15 structures. These closed structures may be small closed loops 6 or bends 8 (FIG. 1B).  
16 Both bends 8 and small closed loops 6 may be formed by bending a wire 5 at a selected  
17 point located between the ends 7 of wire 5 (FIG. 1C shows small closed loops 6). For  
18 most applications, the selected point of the bend or small closed loop may be close to the  
19 midpoint of wire 5, as shown in FIG. 1C with respect to small closed loop 6. FIG. 1C  
20 also shows both ends of wire 5 being located proximate end 2 of body 10 (although the  
21 remainder of body 10 is not shown). Body 10 is formed by plain weaving wires 5, as will  
22 be discussed below in greater detail.

23 Loops 6 and bends 8 provide significant advantages, some of which are  
24 unexpected, over woven devices such as the WALLSTENT that have free wire ends. For  
25 instance, the Wallsten patent recognizes that the free wire ends of the WALLSTENT  
26 should be protected, implicitly acknowledging the potential tissue-damaging dangers such  
27 free, sharp wire ends pose. The Wallsten patent suggests methods by which one can  
28 attempt to lessen these dangers, such as connecting the free wire ends to each other by  
29 attaching U-shaped members to them through heat welding, gluing or the like. These

1 suggested methods can be time-consuming and, as a result, expensive. No such steps  
2 need to be taken in creating either loops 6 or bends 8 of the present woven devices as will  
3 be discussed below in greater detail.

4 Further, the connections resulting from the methods disclosed in the Wallsten  
5 patent are likely more prone to mechanical failure than are loops 6 or bends 8 of the  
6 present woven devices. For example, welding can introduce anomalies such as cracks  
7 (which may result from the non-uniform solidification, uneven boundaries, *etc.*); voids or  
8 other irregularities resulting from porosity; inclusions (which include slag, oxides, *etc.*);  
9 *etc.*, into the welded metal that create stress concentrations and dramatically increases the  
10 propensity for the welded connection to fail at those locations. In contrast, the gentle  
11 curves and bends resulting in loops 6 and bends 8 are virtually free of any such induced  
12 stresses and, as a result, are much less likely to fail.

13 The Wallsten patent also suggests gluing the free wire ends, a method that  
14 provides even less structural integrity than can welding, because the resulting bond  
15 between the joined wire ends is only as strong as the surface tension between the glue and  
16 the metal used. Consequently, the joint created is more prone to failure than a welded  
17 joint suffering from the anomalies just discussed.

18 Similarly, the Wallsten patent discloses first utilizing electric resistance heating to  
19 weld together the points of crossing of the free wire ends in a ring around the stent and  
20 then folding the free wire ends extending beyond the welded ring inwardly with light  
21 plastic deformation through controlled heating. This method involves not only the likely  
22 introduction of the anomalies discussed above that can result from welding, it also  
23 involves an additional stress on the joints created as the free wire ends are folded  
24 inwardly while being heated. Thus, this preferred joint is similar to the glued joint in that  
25 it is likely even more prone to failure than one involving only welding.

26 In sum, the gentle curves and bends that may be used to create loops 6 and bends  
27 8 of the present woven devices provide devices with safer ends: no free wire ends exist  
28 that may unintentionally penetrate and damage the wall of the structure into which they

1 are delivered; the bends 8 or loops 6 are much less likely to mechanically fail than are the  
2 free wire ends that are connected together using welding or glue; and the likely time-  
3 consuming task of creating multiple welded or glued joints does not exist. Further, while  
4 the closed structures 4 (discussed below in greater detail) may be reinforced using  
5 methods similar to those suggested by the Wallsten patent (*i.e.*, such as by welding), the  
6 present woven devices have, at most, only half as many potential locations for using such  
7 methods (and most likely less than half considering fewer wires are generally needed for  
8 making the present stents than are needed for making comparably-sized WALLSTENTS,  
9 even equating one of the present wires to two wires as those are used in the  
10 WALLSTENT). As a result, the potential for mechanical failure of the present woven  
11 devices is reduced accordingly.

12 In addition to the foregoing benefits, loops 6 and bends 8 also provide advantages  
13 over the modified free wire ends disclosed in the Wallsten patent discussed above that are  
14 unexpected. For example, the inventors have found that the mesh of one of the present  
15 woven stents may be formed from fewer wires than can the mesh of a comparably-sized  
16 WALLSTENT (even equating one of the present wires to two wires as those are used in  
17 the WALLSTENT). Accordingly, the expansile force of one of the present woven stents  
18 of a given size may be maintained with fewer wires than would be needed to maintain the  
19 same expansile force of a WALLSTENT of the same size by simply increasing the mesh  
20 tightness (*i.e.*, by increasing angle  $\alpha$ —FIG. 1A—discussed below in greater detail).  
21 Similarly, the inventors have found that the same result may be achieved by increasing  
22 the diameter of the present wires with or without adjusting the mesh tightness. As a  
23 result, the amount of metal needed for the present woven stents may be less than what is  
24 needed in another comparably-sized woven stent, such as the WALLSTENT. This  
25 reduction in necessary metal translates to a cost savings, and, as described above, also  
26 means that patients are less likely to experience thrombosis and/or restenosis. As a  
27 further result, the variety of sizes that may be created for the present stents and the variety  
28 in the tightness of the weave of each is virtually unlimited, thereby facilitating virtually  
29 all potential applications.

1 Further, the inventors also discovered that virtually no shortening occurs while  
2 bending the present woven stents, nor do the diameters of the present woven stents  
3 increase during bending. Thus, it is easier to accurately and predictably position the  
4 present stents in a tortuous anatomy than it is to position other woven stents that shorten  
5 more or suffer larger increases in diameter when bent, such as the WALLSTENT. For  
6 example, a tightly-woven present stent, 2.5 cm long, 10 mm in diameter, formed from 10  
7 0.006-inch wires may be maximally bent by simply holding the two ends thereof between  
8 two fingers and bringing those ends together, and no shortening or diameter increase  
9 occurs during maximal bending. In contrast, for a WALLSTENT formed from 24 0.005-  
10 inch wires to behave similarly, the inventors found that it should be 6 cm long and 9 mm  
11 in diameter; although, when manipulated in a similar manner, the WALLSTENT  
12 experienced a 10% increase in diameter and some shortening. Thus, the length-to-  
13 diameter ratios of the foregoing stents were 2.5 and 6.6, respectively.

14 As few as five wires, and an unlimited maximum number of wires may be used to  
15 form body 10 for any given application. As used herein, "wires" will mean a strand  
16 formed of any material, such as metal, plastic, fiber, *etc.* In an exemplary embodiment of  
17 the present invention, 6 to 12 wires are typically used to form body 10 in most  
18 applications.

19 The number of wires that may be used depends on the application, and specifically  
20 on the desired expansile force of the stent. The expansile force of the stent is the radial  
21 force necessary to reduce the diameter of the stent. Factors affecting the expansile force  
22 of the stent include: the tightness of the weave (which is determined by the number of  
23 wires used and the angle formed by the crossed wires - the more wires or the closer the  
24 angle is to 180°, the tighter the weave), the number of wires used to form the woven stent,  
25 and the diameter of the wires used. When body 10 is used in the coronary artery, for  
26 example, it may be desirable to use the smallest possible amount of wire material to  
27 prevent thrombosis and reduce the possibility of restenosis in the vessel with a relatively  
28 slow circulation.

In FIG. 1A, when body 10 is in its initial, unconstrained shape, angle  $\alpha$  may range from about  $90^\circ$  up to, but not including,  $180^\circ$ . The expansile force of body 10 increases as angle  $\alpha$  approaches  $180^\circ$ . It is to be understood that angles less than  $90^\circ$  may be utilized for angle  $\alpha$ . In an exemplary embodiment, angle  $\alpha$  is preferably obtuse, *i.e.*, more than  $90^\circ$ , and most preferably about  $150^\circ$ . In certain applications, however, a larger expansile force may be desirable, and, thus, angle  $\alpha$  may be closer to  $180^\circ$ , such as in the case of a tumorous stricture or the like. In this regard, in an *in vitro* comparative study, a stent according to the present invention exhibited a higher expansile force and thus a larger capability of withstanding outer compression than both a Z-stent and a WALLSTENT of the same diameter, as revealed in Table 1, below. In Table 1, the designation  $\Delta$  in the leftmost column represents the circumferential displacement (in mm) of the stent in question. For example, a  $\Delta$  of 2 mm indicates that the circumference of the stent in question was reduced by 2 mm, and the force necessary to effect that displacement was then recorded. The designation "W" refers to the WALLSTENT.

Table 1 – Comparison of Expansile Forces of a Z-Stent,  
a WALLSTENT and a Nitinol Woven Stent

$\Delta$ (mm)	Z Center	Z Between	Z Side by Side	W Center	W Overlap	W Side by Side	Woven Stent
2	16	13	19	15	35	18	44
4	36	28	31	25	59	22	91
6	51	44	42	42	80	35	126
8	63	61	56	50	108	42	158
10	81	79	62	60	126	48	167
12	100	98	76	74	149	54	175
14	115	119	90	84	170	63	184
16	127	133	101	100	197	73	202
18	146	192	122	111	220	84	
20	165	unmeasur.	142	129	248	96	

With respect to Table 1, the unit "g" for "grams" is used as a measure of force. Although the correct unit of force is the "dyne", which is equal to the mass in grams multiplied by the gravitational constant, the inventors believe that the average reader will

1 have a better idea about the size of force when the associated mass unit (grams) is  
2 specified.

3 When one uses, *e.g.*, a WALLSTENT or other commercially available stent for  
4 stenting, the manufacturer usually recommends to use a stent one mm larger than the  
5 diameter of the vessel, after precise determination of the size of the vessel, to eliminate  
6 the magnification factor caused by the fluoroscopy/radiography. This minimal  
7 "overstenting" is used to achieve good contact between the stent and the vessel wall. The  
8 manufacturer also typically provides exact data regarding the relationship between the  
9 stent's diameter and length to facilitate precise positioning thereof. The woven nitinol  
10 design of the present invention has significantly greater expansile force than that of the  
11 WALLSTENT if a comparable number of wires are used to form the same caliber stent  
12 (understanding that one wire as used herein and shown in FIG. 1C would require the use  
13 of two wires in the WALLSTENT, given the free, unclosed wires thereof). Compared to  
14 the WALLSTENT, the closed structures of the stents of the present invention and the  
15 better shape memory of the wires that may be used may result in a considerable reduction  
16 in the size of the wires used, in the number of wires used, as well as in the angles between  
17 the wires. For instance, in small vessel applications (*e.g.*, coronary artery) it is  
18 advantageous to use the minimum amount of wire (metal) to reduce the possibility of  
19 thrombosis and/or restenosis. Furthermore, in preferred embodiments, angle *a* may be  
20 reduced below 90 degrees without losing the necessary expansile force for self anchoring.  
21 For the same vascular application, the same or even greater expansile force can be  
22 achieved with a loosely-woven nitinol design of the present invention compared to the  
23 WALLSTENT and other available stents. A stent of the present invention may also be  
24 chosen so as to have a diameter approximately ten percent larger than the diameter of the  
25 tubular structure to be stented.

26 Body 10 may also be formed from a single wire ("the single wire embodiment").  
27 The single wire embodiment is illustrated in FIG. 1C, wherein wire ends 7 have not yet  
28 been twisted or coupled together to form a closed structure 4, as described below in  
29 greater detail. One version of the single wire embodiment is illustrated in FIG. 50A. As

1 illustrated in FIG. 50A, body 10 of the stent has an axis 810, distal end 12 and proximal  
2 end 2. First segment 812 of wire 5 is separated from second segment 814 by either bend  
3 8 (not shown) or closed loop 6. As shown in FIG. 50A, first segment 812 extends  
4 helically in a first direction around axis 810 toward end 2, and second segment 814  
5 extends helically in a second direction around axis 810 toward end 2. First segment 812  
6 crosses second segment 814 in a number of locations 816. As shown in FIG. 50A,  
7 locations 816 define loops 818, which touch each other such that the loops are  
8 contiguous. Loops 818 are "contiguous" because, with the exception of the first and last  
9 loops, each loop shares a point--location 816--with two other loops.

10 Segments 812 and 814 may be arranged in two different ways with respect to each  
11 other. As shown in FIG. 50A, segment 812 is positioned farther from axis 810 than  
12 segment 814 at each location 816, while in FIG. 50B, segments 812 and 814 alternate  
13 being further from axis 810 at each location 816. It will be understood to those of skill in  
14 the art, with the benefit of this disclosure, that segment 812 may be positioned farther  
15 from axis 810 than segment 814 at one or more locations 816.

16 In the single wire embodiment of the stents in FIGS. 50A and 50B, loops 818  
17 reside in a series of planes that includes two groups of planes (not shown), one of which  
18 includes the planes passing through the first, third, fifth, *etc.* loops 818, and the other of  
19 which includes the planes passing through the second, fourth, sixth, *etc.* loops 818. The  
20 planes in each group are roughly parallel to each other. When body 10 is in its  
21 unconstrained state, the planes in one of the groups intersect the planes in the other group  
22 at acute angles falling within the range of slightly greater than 0° to about 45°. Axis 810  
23 passes generally through the center of each of loops 818.

24 As shown in FIG. 50C, certain of loops 818 of the single wire embodiment of  
25 body 10 of the stent may be separated by longitudinal segments in which segments 812  
26 and 814 are twisted together. As shown, pairs of contiguous loops 818 -- with the  
27 exception of the loop located after closed loop 6 -- are separated by twisted segments 820.  
28 Although not shown, it will be understood to those of skill in the art, with the benefit of



1 this disclosure, that as many contiguous loops as are desired may be separated by a  
2 twisted segment **820** from another loop or any other number of contiguous loops to suit a  
3 particular application. For example, three contiguous loops may be separated from  
4 another loop or two or more other contiguous loops by a twisted segment in the same  
5 manner that the pairs of contiguous loops are separated by twisted segments as illustrated  
6 in **FIG. 50C**. Similarly, four contiguous loops may be separated from another loop or  
7 two or more other contiguous loops by a twisted segment. As yet another example, a  
8 single wire embodiment stent may have only one twisted segment separating two groups  
9 of five contiguous loops.

10 In contrast to the "hoop stent" disclosed in U.S. Patent No. 5,830,229 to Konya *et*  
11 *al.* ("the hoop stent"), which is incorporated herein by reference, the single wire  
12 embodiment of the stent that has twisted segments **820**, depicted in **FIG. 50C** for  
13 example, possesses multiple contiguous loops **818**. As a result, the single wire  
14 embodiment stents with such twisted segments are more resistant to forces compressing  
15 loops **818** in a lateral manner. The directions of such lateral forces are indicated by the  
16 large arrows in **FIG. 50C**. As a result, if the single wire embodiment of the stent having  
17 multiple contiguous loops, such as the stent depicted in **FIG. 50C**, is placed in a vessel or  
18 other structure that is sometimes bent or flexed, that vessel or structure will more likely  
19 remain patent when bent or flexed than it would were it supported by the hoop stent.

20 Body **10** of a stent according to the present invention may be formed by various  
21 methods of plain weave including hand weaving and machine weaving. The following  
22 process is an exemplary embodiment of plain weaving according to the present invention.  
23 As shown in **FIG. 16**, a template **300** having a diameter corresponding to the chosen  
24 diameter of body **10** is provided. The top of the template is equipped with holes **302**  
25 around its circumference. Pins **304** are placed through the holes such that they extend  
26 beyond the outer surface of the template on opposing sides. As shown in **FIG. 16**, wires  
27 **5** are bent at about their midpoint around the pins. This bending may result in the  
28 formation of bend **8** as shown, or wires **5** may be wrapped around the pins to form small  
29 loops **6** (not shown). In one embodiment of body **10**, angle **b** of small closed loop **6** or

1 bend 8 (**FIG. 1A**) may be less than 90°. In a more typical embodiment of body 10,  
2 angle **b** may be equal to or greater than 90°, and may approach, but not include, 180°. In  
3 an even more typical embodiment, angle **b** may be about 140-160°. As discussed above,  
4 bends 8 and loops 6 are created in a manner that makes them likely more mechanically  
5 sound than the joints disclosed in the Wallsten patent created by connecting two wire  
6 ends together through welding or gluing.

7 In one embodiment of the present plain weaving process, the ends of two wires 5  
8 may be coupled together and placed around pin 304, instead of bending a single wire 5 as  
9 above described. This coupling may be achieved by using any suitable means capable of  
10 preventing the wires from returning to their straight, unbent configuration. As shown in  
11 **FIG. 30A**, such means include bending and crimping a metal clip around the wires. In  
12 another embodiment of the present plain weaving process, as shown in **FIG. 30B**, two  
13 wires 5 may each be wrapped around pin 304 separately and secured using any suitable  
14 means, such as those just described, in further contrast to bending one wire around pin  
15 304. After annealing (*i.e.*, heating and cooling) wires 5 shown in **FIG. 30B** as described  
16 below, the two wires may be coupled to each other using any suitable means such as  
17 twisting, crimping or tying as further below described.

18 Although only two pins are shown in **FIG. 16**, it is to be understood that this is  
19 done for illustrative purposes only, and not to indicate the appropriate number of wires to  
20 use in any given application. In an exemplary embodiment, template 300 is typically  
21 formed of brass or copper, but may be formed of any suitable material capable of  
22 withstanding the cure temperature below discussed, such as stainless steel. Similarly, in  
23 an exemplary embodiment, pins 304 are typically formed of stainless steel, but may be  
24 formed of any similarly suitable material. It is to be understood that the pins may be  
25 supported by the template by any suitable means capable of withstanding the cure  
26 temperature, including preforming, attachment by welding, threading, or the like.

27 As shown in **FIG. 17**, after the wires have been bent around the pins, the wires are  
28 secured to the template to prevent them from returning to their original, straight, unbent

1 position. This may be necessary given the superelastic nature of wires such as nitinol and  
2 the like (discussed below). As shown in FIG. 17, wires 5 are secured by securing wire  
3 306 around the outside of wires 5 so as to secure wires 5 against the outside of the  
4 template. In an exemplary embodiment, copper is typically used for securing wire 306,  
5 but it is to be understood that any suitable wire capable of withstanding the annealing  
6 temperature of about 500°C discussed below may be used. After the wires are secured,  
7 small weights 360 (shown in FIG. 20) are attached to the free ends of the wires using any  
8 suitable means such as tying, or the like. In an exemplary embodiment, weights with  
9 masses of approximately 50-100 grams may typically be used with wires having  
10 diameters of between about 0.005 inches and about 0.011 inches. However, it is to be  
11 understood that weights of different masses may be chosen so long as the wires are kept  
12 under tension (*i.e.* straight) during plain weaving (as described below), and properly  
13 balance the central weight (described below).

14 As shown in FIG. 18, a stand 330 with a circular plate 320 is provided with an  
15 opening 325. The diameter of the opening may depend on the diameter of the template.  
16 In an exemplary embodiment, an opening with a diameter of about 4.5 cm may be  
17 typically utilized in conjunction with a template of about 1.0 cm. It is to be understood,  
18 however, that an opening with a diameter more closely corresponding to the diameter of  
19 the template may be utilized.

20 As shown in FIG. 19, before or after the weights are attached to the ends of wires  
21 5, the template is inverted. In an exemplary embodiment, the weights may be typically  
22 attached to the free ends of the wires prior to inversion of the template such that the wires  
23 are kept under tension and may be prevented from returning to their unbent, nominal  
24 state. A central weight 340 may then be attached to the end of the template. In an  
25 exemplary embodiment, the central weight may be typically hung from the pins.  
26 However, it is to be understood that the central weight may be attached to the template's  
27 end in any suitable manner, such as hanging from holes in the template itself, *etc.*

1 Before or after central weight 340 is attached to the end of the template, the-  
2 inverted template is placed through opening 325, as shown in FIG. 20. In an exemplary  
3 embodiment, the central weight may typically be attached to the inverted template after  
4 the inverted template is placed through opening 325. As shown in FIG. 20, the wires 5  
5 may be arranged fairly evenly around the circumference of the circular plate. As shown  
6 in FIG. 21, in an exemplary embodiment of the present invention, 6 wires having 12 ends  
7 numbered 1-12 (each wire having 2 ends) are shown as being arranged in a substantially  
8 symmetrical fashion around circular plate 320. The weights 340 and 360 typically serve  
9 to keep the wires under tension and in balance. Next, the plain weaving may take place.

10 In the manner shown in FIG. 22, the weave may be started by crossing one wire  
11 end over the adjacent wire end. This crossing may be made in either a clockwise or  
12 counterclockwise fashion. This crossing may be carried out as directed by the arrows  
13 shown in FIG. 22. After a complete set of crosses (or one "turn") has been carried out,  
14 the location of the crossed wire ends is as shown in FIG. 23. In an exemplary  
15 embodiment, the resulting location of the wire ends may be achieved by crossing one wire  
16 end over another in one direction while slightly shifting the wire end not crossed in the  
17 opposite direction. In an exemplary embodiment, this shifting may be about 15°. Thus,  
18 wire end 1 may be crossed in a clockwise direction over wire end 2, while shifting wire  
19 end 2 about 15° counterclockwise. Once one turn has taken place, crossing may begin in  
20 the same fashion, but in the opposite direction, as shown in FIG. 24. This process may  
21 be repeated until the plain weave is complete.

22 The tightness of the plain weave (*i.e.*, the angle  $\alpha$  between the wires - FIG. 1A)  
23 may be adjusted by changing the central weight. An increase in the central weight results  
24 in a looser weave (decreased angle  $\alpha$  between the wires) and vice versa. Upon  
25 completion of the plain weave, the adjacent wire ends may be closed as below described.

26 In an exemplary embodiment according to the present invention, a conventional  
27 braiding machine may be utilized to arrange wires 5 in a plain weave to form body 10 of a  
28 stent or any other device described herein. Such a braiding machine may be obtained, for

1 example, from Wardwell Braiding Machine Company in Central Falls, RI. The manner  
2 in which a plain weave may be achieved using a conventional braiding machine is  
3 displayed in **FIG. 7** of U.S. Patent No. 5,419,231 to Earle, III *et al.* (1995), which is  
4 hereby expressly incorporated by reference, as well as in **FIG. 1** of U.S. Patent No.  
5 5,485,774 to Osborne (1996), which is hereby expressly incorporated by reference.

6 After the plain weave process is complete, as shown in **FIG. 1A**, at the rear or  
7 proximal end **2** (the end closest to the surgeon/operator) of body **10**, wire ends **7** may be  
8 twisted together using multiple twists so as to form closed structures **4**. In an exemplary  
9 embodiment, as few as 2 twists may be used, and as many as about 6. In an exemplary  
10 embodiment, it is preferable to keep the twisted wire ends as short as possible. The  
11 shorter the twisted wire ends are kept, the more resistant to bending the twisted wire ends  
12 are. As a result, the twisted wire ends are less likely to be inadvertently displaced during  
13 placement, repositioning, or retrieval, thus reducing the potential for causing tissue  
14 damage. Although not shown, it will be understood to those of ordinary skill in the art  
15 with the benefit of the present disclosure that the wire ends may be coupled together,  
16 instead of by twisting, using any suitable means capable of withstanding the heating  
17 described below, such as bending and crimping a metal clip around the wires, tying them  
18 together with suitable material such as stainless steel wire, welding, *etc.*

19 Other configurations of template **300** may also be utilized consistently with the  
20 present disclosure. For example, template **300** may be provided not only with pins **304** or  
21 tabs **600** (described below), around which wires **5** are bent, wrapped, tied, twisted, *etc.*,  
22 prior to weaving the body of the stent (or the bodies of any of the woven structures  
23 disclosed herein), but may also be provided with pins around which the wire ends may be  
24 twisted in fashioning closed structures **4**. Finish pins **800** may be supplied on a ring, such  
25 as ring **802** depicted in **FIG. 48**, in any suitable fashion, including, for example, through  
26 removable or permanent attachment. Ring **802** may be configured to threadably engage  
27 template **300** as depicted in **FIG. 48**. In other embodiments, ring **802** may be configured  
28 to engage template **300** by virtue of frictional forces (not shown) or may be configured to  
29 be secured to template **300** as would a clamp (not shown). Finish pins **800** may also be

1 engaged with template 300 in the same manner as pins 304. As shown in FIG. 49, in  
2 such an embodiment, template 300 may be provided with finish holes 804 similar to holes  
3 302, and finish pins 800 may be placed through finish holes 804. Ring 802 may also be  
4 utilized in place of holes 302 and pins 304.

5 In an embodiment in which finish pins 800 are engaged with template 300 through  
6 the utilization of ring 802, the number of finish pins utilized may be equal to the number  
7 of wires 5 that are used. Template 300 may be threaded along any portion of its length so  
8 as to best accommodate a variety of woven body sizes. For example, only a portion of  
9 template 300 may be threaded, as depicted in FIG. 49. Threads need not be utilized with  
10 a ring that engages template 300 by virtue of frictional forces.

11 Advantageously, the use of ring 802 allows for the easy and precise alignment of  
12 pins 304 or tabs 600 with finish pins 800. Another advantage afforded by the use of ring  
13 802 is the ease with which the precise length of the woven body may be achieved. The  
14 length of the woven body may be achieved by adjusting and fixing the distance along the  
15 length of template 300 between pins 304 or tabs 600 and finish pins 800. In an  
16 embodiment in which finish pins 800 are placed through finish holes 804, the number of  
17 finish pins utilized may be equal to one-half of the number of wires 5 that are used, since  
18 both ends of the finish pins will be utilized. Template 300 may be provided with finish  
19 holes 804 along any portion of its length so as to best accommodate a variety of woven  
20 body sizes. For example, only a portion of template 300 may be provided with finish  
21 holes 804, as depicted in FIG. 49.

22 As with ring 802, the use of finish holes 804 advantageously allows for the easy  
23 and precise alignment of pins 304 or tabs 600 with finish pins 800. Additionally, the  
24 precise length of the woven body may advantageously be achieved by virtue of the  
25 distance along the length of template 300 between pins 304 or tabs 600 and finish holes  
26 804 (and, therefore, finish pins 800.)

27 With finish pins 800 in place, once the wire ends of wire(s) 5 have been woven  
28 around template 300, the wire ends may be secured around finish pins 800 in any suitable

1 manner to form closed structures 4, including by twisting, bending, wrapping and the like.  
2 In one embodiment, the wire ends may be crossed, then bent around finish pins 800 and  
3 then secured together using a short piece of a thin-walled metal tubing. Such a joint may  
4 then be reinforced by soldering, welding, or the like. A suitable number of additional  
5 twists may be utilized after securing the wire ends around finish pins 800 in forming  
6 closed structures 4. Securing wire 306 (not shown) may be utilized to secure closed  
7 structures 4 to template 300 during annealing.

8 As a result of securing the wire ends around finish pins 800, the angle created  
9 between the crossed wire ends may be similar, if not identical to, angle b described  
10 above. Advantageously, by using finish pins 800, this angle between the crossed wire  
11 ends may be maintained, preventing the weave of the woven body from loosening. Were  
12 loosening to occur, the expansile or radial force of the portion of the body with the  
13 loosened weave could decrease, causing that portion of the woven body to remain  
14 elongated within the structure in which it is placed. Therefore, through the use of finish  
15 pins 800 and as a result of the correlating maintenance of the angle between the crossed  
16 wire ends that are wrapped or twisted around the finish pins, the tightness of the weave  
17 along the length of the woven body – from end to end – may be consistent and resistant to  
18 loosening, and the expansile force of the end of the woven body having closed structures  
19 4 may be comparable to the expansile force of the other portions of the woven body.

20 Another method of creating body 10 of a stent according to the present invention  
21 is illustrated in FIGS. 37-47B. As shown in FIG. 37, the base of template 300 may be  
22 equipped with longitudinal tabs 600 formed by two longitudinal cuts connected by a  
23 transverse cut. The length of the cuts may be determined based upon the size of the  
24 template chosen. For example, a template that is about 10 mm in diameter may have  
25 longitudinal tabs with longitudinal cuts about 4 to 5 mm long, and the connecting  
26 transverse cuts may be about 2 mm long. As illustrated in FIGS. 37, tabs 600 may be  
27 slightly elevated from the surface of template 300 and may be positioned equally around  
28 template 300.

1        **FIGS. 37 and 38A and B** also illustrate that wires 5 may be bent around tabs 600  
2        at selected points located between the ends of the wires to form bent portions along wires  
3        5. The bent portions may take the form of bends 8, as shown in **FIG. 38A**, or may be  
4        further wrapped around tabs 600 to form loops 6, as shown in **FIG. 38B**. Angle **b** of  
5        bends 8 or loops 6 may be less than 90°. In a more typical embodiment of body 10, angle  
6        **b** may be equal to or greater than 90°, and may approach but not include, 180°. The bent  
7        portions may be arranged to define end 12 of body 10. Wire ends 7 of wires 5 may then  
8        be weaved to create body 10 using, for example, the following machine weave method.

9        As shown in **FIG. 39**, ends 7 of each wire 5 may be arranged around a pair of  
10        bobbins 602. The length of the wire wound around each bobbin may be determined by  
11        considering the total length of the wire needed to form body 10 as well as the wire length  
12        needed to arrange the bobbins around weaving plates (shown in **FIG. 40**), which are  
13        discussed below in greater detail.

14        As shown in **FIG. 40**, in one embodiment in which bobbins 602 are utilized, two  
15        coaxially arranged weaving plates may be utilized. As shown in **FIG. 41**, upper weaving  
16        plate 604 and lower weaving plate 606 may be positioned in different horizontal planes.  
17        **FIG. 41** illustrates that the weaving plates may be equipped with multiple bobbin rods  
18        608, the axes of which are substantially perpendicular to the weaving plates, on which  
19        bobbins 602 may be slidably secured. (**FIG. 41** depicts only 4 bobbins for the sake of  
20        simplicity.) The weaving plates may be provided with holes therein through which  
21        template 300 and/or wires 5 may pass, as shown in **FIG. 41**. Template 300 may be  
22        secured to the base of the weaving machine chosen using any suitable means such as  
23        template rod 610, around which template 300 may pass, as shown in **FIG. 41**. Template  
24        300 may be secured to the base of the weaving machine chosen using any suitable means  
25        such as template rod 610, around which template 300 may be slidably placed (**FIG. 35**).  
26        Template rod 610 may be configured to firmly engage template 300 through frictional  
27        forces (e.g., by tapering template rod 610). Instead of template rod 610, any appropriate  
28        lock mechanism may be used to secure the base of the weaving machine to template 300.



1           As shown in **FIGS. 42A** and **43A**, the pairs of bobbins **602** may be prepared for  
2           weaving by arranging one bobbin on upper weaving plate **604** and the other bobbin from  
3           the pair on lower weaving plate **606**. Wires **5** may then be bent around tabs **600**, and the  
4           ends of the wires may be attached to bobbins **602** using any suitable means capable of  
5           holding wires **5** under tension throughout the weaving process. An example of such a  
6           mechanism is a one-way brake that allows bobbin **602** to rotate in a single direction only,  
7           such that the wire **5** may wind off bobbin **602**. Simultaneously, such a brake may be  
8           configured so as to continuously maintain tension in wire **5** by virtue of the brake's  
9           resistance to the winding off of wire **5**.

10           As shown in **FIG. 42A**, with the wire ends in place, the weaving may begin by  
11           crossing the wire ends of the same wire, which results in the formation of a small caliber  
12           loop **6** (**FIG. 42B**) at the site of the bent portion. In another manner of weaving  
13           illustrated in **FIG. 43**, the wire ends of different wires may be crossed first, resulting in  
14           bend **8** at the site of the bent portion (**FIG. 43B**).

15           As shown in **FIGS. 44-45**, the two weaving plates may be arranged such that the  
16           surfaces thereof from which the bobbin rods extend face each other. In this alternative  
17           embodiment, the diameters of the plates may be the same or different. Wires **5** may be  
18           arranged on bobbins **602** in the same manner as described above, as shown in **FIG. 45**.

19           Despite which of the aforementioned weaving plate arrangements is utilized, the  
20           weaving plates rotate in opposite directions during the weaving process. The weaving  
21           plates may be operated at any suitable speed. In this regard, a speed as low as 1 to 10  
22           cycles per minute is acceptable. The weaving plates may also be driven by hand.

23           The weaving plates may supported and rotated using any suitable means. **FIG. 61**  
24           illustrates one means of supporting and rotating weaving plates **604** and **606**. (**FIG. 61**  
25           depicts on 4 bobbins for the sake of simplicity.) As shown, weaving plate supporter **650**  
26           may be equipped with lower arm **652** and upper arm **654** for supporting lower and upper  
27           weaving plates **606** and **604**, respectively. Weaving plate drivers **660** may be secured to  
28           the upper and lower arms of the weaving plate supporter and engaged with the weaving

1 plates in order to operate them. The drivers may be configured to operate in any suitable  
2 fashion. For example, the drivers may be configured with a power source and provided  
3 with gears of any suitable configuration for causing the weaving plates to rotate. The  
4 drivers may also be configured to utilize magnetism or electromagnetism to rotate the  
5 weaving plates. The drivers may be also be configured such that the weaving plates may  
6 be rotated by hand. Further, although not shown, it will be understood to those of skill in  
7 the art, with the benefit of this disclosure, that either or both of the upper and lower arms  
8 may be provided with branches to which drivers may be attached. The drivers on the  
9 branches could then be secured to or engaged with the top surfaces of the weaving plates  
10 in the same fashion that drivers 660 are engaged with the bottom surfaces of the weaving  
11 plates as shown in FIG. 61. Thus, in such an embodiment, both the top and bottom  
12 surfaces of each weaving plate would be engaged with drivers.

13 A braiding machine suitable for carrying the weaving process just described (*i.e.*,  
14 utilizing the weaving plates) may be obtained; for example, from Wardwell Braiding  
15 Machine Company in Central Falls, RI.

16 After the weaving process is complete, wire ends 7 may be twisted together or  
17 coupled as described above to form closed structures 4. To make the process of wire  
18 twisting faster and easier, the wires may be twisted with a special hand tool designed for  
19 this purpose. Tool 612 illustrated in FIG. 46A follows the principle of an automatic  
20 pencil. Jaws 614 of tool 612 are configured so that wire ends 7 may be firmly held  
21 between jaws 614. Jaws 614 may be activated by push button 616 moving against spring  
22 618. After placing wire ends 7 into pre-formed gaps 620 located between jaws 614 (FIG.  
23 46B), spring 618 expands (or returns to its unconstrained state) and retracts jaws 614,  
24 securing wire ends 7 firmly between jaws 614 due to the pressure of outer housing 622  
25 acting to close jaws 614. Outer housing 622 may then be rotated to create multiple twists  
26 of wire ends 7. As illustrated in FIGS. 47A and 47B, the twisted ends of body 10 may be  
27 secured to template 300 using transverse tabs 624, which may be formed the same way as  
28 longitudinal tabs 600.

Turning to the single wire embodiment, body 10 may be formed using either the hand weaving process or the machine weaving process, both of which are described above. In preparation for the weaving process, template 300, which may be configured to have any suitable shape, may be provided with pin 304 or longitudinal tab 600 near the end thereof at which the weaving is to begin. Near its other end, template 300 may be provided with finish pin 800 or transverse tab 624, which may be appropriately aligned with pin 304 or longitudinal tab 600. In one embodiment, finish pin 800 may be provided on ring 802.

The weave of body 10 may then be started by bending wire 5 around pin 304 or longitudinal tab 600 to form either bend 8 or closed loop 6. In an exemplary embodiment, securing wire 306 may be utilized to secure bent wire 5 to template 300 as described above. The two segments of wire 5 on either side of bend 8 or closed loop 6 may then be woven to create body 10 by helically wrapping the segments around template 300 in opposite directions toward finish pin 800 or transverse tab 624. The segments may be crossed over each other during the process in alternating fashion to result in the single wire embodiment depicted in FIG. 50B. This weaving may take place either by hand or using the weaving templates described above.

After the weaving is complete, in one embodiment, closed structure 4 may be created by wrapping the wire ends around finish pin 800 in the manner described above. In another embodiment, the wire ends may be twisted or coupled together as described above to form closed structure 4, which may then be secured to transverse tab 624. It will be understood that additional pins 304 or longitudinal tabs 600 may be utilized to create the single wire embodiment. Such additional pin(s) or tab(s) may be vertically aligned with the other pin or longitudinal tab such that multiple closed loops 6 may be formed at the end of body 10 where the weave begins, as depicted in FIG. 50B. Similarly, additional finish pins or transverse tabs may be utilized in the same fashion. The use of pin(s) 304 or longitudinal tab(s) 600 with finish pin 800 or transverse tab 624 will advantageously ensure that wire 5 remains in position during annealing. The annealing processes described below may be utilized for annealing the single wire embodiment.

1           After the plain weave of wires 5 is completed on the template, if the wires are  
2       made of a material that can be programmed with either thermal shape memory or  
3       superelasticity such as nitinol or other shape memory materials described below, body  
4       10/template unit may be heated so as to program body 10 with either thermal shape  
5       memory or superelasticity. If body 10 is programmed with superelasticity, its initial  
6       shape can be deformed by applying a force thereto. After removal of the force, body 10  
7       may substantially recover its initial shape. If body 10 is programmed with thermal shape  
8       memory, its initial shape can be deformed upon application of a force at a first  
9       temperature. The force may be removed, and body 10 may remain deformed until heated  
10      to a second temperature. At the second temperature, body 10 may substantially recover  
11      its initial shape.

12           In programming body 10 with superelasticity, the body 10/template unit may be  
13      heated to about 500°C for about 5 to 15 minutes, typically about 12 to 15 minutes, and  
14      even more typically for about 15 minutes, in an oven. After allowing the unit to cool to  
15      room temperature, wires 5 possess superelastic properties. In an exemplary embodiment,  
16      natural cooling is typically used. It is to be understood, however, that accelerated cooling  
17      using a fluid bath, for example, may be utilized resulting in slightly different superelastic  
18      characteristics than are achieved with natural cooling. In programming body 10 with  
19      thermal shape memory, the body 10/template unit may be heated to about 500°C for  
20      about 60 to 120 minutes, typically about 120 minutes, in an oven. After allowing the unit  
21      to cool to room temperature, wires 5 possess thermal shape memory. In an exemplary  
22      embodiment, natural cooling is typically used. It is to be understood, however, that  
23      accelerated cooling using a fluid bath, for example, may be utilized resulting in slightly  
24      different thermal shape memory characteristics than are achieved with natural cooling.

25           In an exemplary embodiment of body 10, it is preferable to further reinforce the  
26      coupled wire ends of closed structures 4 after body 10 has been properly annealed  
27      (especially if twisting was utilized). This reinforcement may be accomplished by any  
28      suitable means such as point welding, soldering, pressure welding, or the like. The wire  
29      ends of closed structures 4 may be soldered by removing any oxide layer that may have

1 formed over the relevant portions of the wires used, and applying solder to those portions.  
2 Soldering may be enhanced by first wrapping the coupled wire ends of the closed  
3 structures 4 with thin stainless steel wires. In an exemplary embodiment, point welding is  
4 preferred to soldering, because point welding is easier to perform than soldering, and may  
5 be more suitable with regard to long-term implantation of the stent.

6 The wires of body 10 may be constructed of any material compatible with the  
7 tissue in which the stent will be placed. Further, the material may be suitably rigid and  
8 elastic and capable of being programmed with either superelasticity or thermal shape  
9 memory. The materials may, for example, be NiTi alloys like nitinol. Such alloys can be  
10 heated and allowed to cool to room temperature, resulting in the alloys having either  
11 superelastic or thermal shape memory properties, depending on the heating time as above  
12 described. Other alloys that may be used include FePt, FePd, and FeNiCoTi. These  
13 alloys may be heat treated to exhibit thermoelastic martensitic transformation, and,  
14 therefore, good thermal shape memory. Other alloys such as FeNiC, FeMnSi, and  
15 FeMnSiCrNi do not possess long-range order and undergo nonthermoelastic  
16 transformation, and, thus, may also be used. Additionally, some  $\beta$ -Ti alloys and iron-  
17 based alloys may also be used.

18 In an exemplary embodiment, nitinol possessing about 55 to 56 % Nickel, and 45  
19 to 44 % Titanium, may be used for wires 5 of body 10. Such nitinol wires are  
20 commercially available from Shape Memory Applications in Santa Clara, CA.

21 When using nitinol wire, the radiopacity of body 10 advantageously increases  
22 over the radiopacity of stents formed using materials such as stainless steel. The  
23 radiopacity depends primarily on the diameter of the nitinol wires and the tightness of the  
24 plain weave created by the wires. The radiopacity of body 10 can be increased further by  
25 using silver solder to reinforce the coupled wire ends forming closed structures 4.

26 The wire sizes that may be used for the stents of the present invention vary  
27 depending on the application of the stent. In an exemplary embodiment, small stents  
28 ranging from about 2 to about 4 mm in diameter and about 1 to about 2.5 cm in length,

1 typically for coronary application, may utilize wires from about 0.003 to about 0.006  
2 inches in diameter. In an exemplary embodiment, medium stents ranging from about 4.5  
3 to about 10 mm in diameter and about 2 to about 10 cm in length, such as are used in the  
4 iliac artery, femoro-popliteal artery, carotid artery, and the renal artery, may utilize wires  
5 from about 0.006 to about 0.009 inches in diameter. In an exemplary embodiment, large  
6 stents above about 10 mm in diameter may utilize wires from about 0.006 to about 0.012  
7 inches in diameter. Applications for the large stents include the aorta (typically a vessel  
8 diameter in about the 20 to 40 mm range), the inferior vena cava ("IVC"), which is  
9 usually less than about 28 mm in diameter, the superior vena cava ("SVC"), the  
10 esophageal (20-25 mm in diameter), and the colon, which may be about 15 to about  
11 25 mm.

### 12 *Tapered Stents*

13 With reference to the illustrative embodiment shown in FIG. 14, there is shown a  
14 tapered stent for insertion and delivery into an anatomical structure. Tapered body 100  
15 may be formed using plain weave by the methods above described. Potential  
16 embodiments of tapered body 100 include the single wire embodiment. The types of  
17 applications for which a tapered stent may be used include the ilio-femoral, femoro-  
18 popliteal arteries, as well as in the carotid arteries for stenting long lesions.

19 The tapered configuration may be achieved different ways. In a first method using  
20 the hand weave method or any of the machine methods described above, a template may  
21 be chosen possessing an appropriate taper. In an exemplary embodiment, a template with  
22 a smooth, contiguously decreasing diameter without steps is typically used. The shape of  
23 the template may correspond roughly to the inner shape of the tapered stent. The shape of  
24 the tapered stent may be chosen based on the shape of the vessel or structure into which it  
25 will be placed.

26 In an exemplary embodiment, it may be preferable to choose a shape for the  
27 tapered stent (and, thus, for the template) such that a "wedge-effect" will be achieved  
28 between the tapered stent and the vessel or structure into which it is placed. The wedge-

1 effect may be used to fix the stent in position and prevent it from distal migration. It is to  
2 be understood, however, that any suitable means for improving the fixation of the stent in  
3 the vessel or structure, such as flaring the proximal end of the stent, may be used in  
4 addition to or instead of the wedge-effect.

5 Using such a template and either hand or machine weave, the weave may be  
6 substantially uniform along the axial length of the stent. As a result of the substantially  
7 uniform weave, the expansile force of the stent may be substantially uniform along the  
8 axial length of the stent. Although the expansile force may be substantially uniform as  
9 stated, the match between the diameters of the tapered stent and the vessel into which the  
10 stent is placed may result in the vessel being exposed to a force lesser than would be  
11 exhibited by a straight stent.

12 In another embodiment according to the present invention, a template possessing a  
13 uniform diameter as described above may be chosen for use with either the hand weave  
14 method or a machine method. The diameter of this template may correspond to the  
15 diameter of the largest portion of the stent. Tapered body 100 may be woven around this  
16 template and heated and cooled as above described. The wire ends of closed structures  
17 104 may then be reinforced as needed for the application. Tapered body 100 may then be  
18 mounted on a tapered template in a fashion similar to the one described above (*e.g.*, using  
19 a copper wire), and reheated in a manner similar to the original heating. Forming the  
20 stent in this manner results in a contiguously loosening mesh toward the tapered end of  
21 the stent. That is, angle  $\alpha$  is contiguously decreased toward the distal end 102 of tapered  
22 body 100 resulting in a decreasing expansile force of the tapered stent towards the tapered  
23 distal end 102.

24 It is to be understood that if a stent (or any other device disclosed herein) is  
25 remodeled a number of times and it is not intended that the stent be programmed with  
26 thermal shape memory, care should be taken not to exceed a total heating time (which  
27 includes the first heating time *and* the second heating time, *etc.*) of about 60 minutes,  
28 because at about 60 minutes, the stent may be programmed with thermal shape memory.

1 As with body 10, one or more of the coupled wire ends of tapered body 100 may  
 2 be left slightly longer than the others and bent inward so as to allow for retrieval of the  
 3 stent using a foreign body retrieval device. Further, closed structures 104 of body 100  
 4 may be flared to improve stent fixation.

5 In an *in vitro* study, the expansile force of the tapered stent of the present  
 6 invention was found to be proportional to the weave tightness. The results of this study  
 7 are set forth below in Table 2. The tightness of the weave is strongly associated with the  
 8 angle between the crossing wires as well as with the number of wires used for creating the  
 9 weave. The stents used in the study were built from 0.011 inch nitinol wires. If the  
 10 angles between the crossing wires are wide (closer to 180°), the stent is better able to  
 11 withstand any outer compression. An increase in the diameter of the nitinol wire would  
 12 increase the expansile force of the stent.

13 Table 2 - Taper-Shaped Self-Expanding Repositionable  
 14 Stent Comparative Study, Using 0.011" Diameter Wires

$\Delta$ (mm)	10 Wires, Tight Weave	8 Wires, Moderate Weave	6 Wires, Loose Weave	6 Wires, Tight Weave
2	115	91	26	92
4	176	123	55	103
6	208	141	74	119
8	238	158	92	126
10	273	170	103	136
12	293	186	120	145
14	331	202	129	153
16	371	223	146	171

15  
 16 With respect to Table 2, the inventors used the unit "g" for "grams" as the  
 17 measure of force for the reasons discussed above. Similarly, the designation  $\Delta$  in the  
 18 leftmost column of Table 2 represents the circumferential displacement (in mm) of the  
 19 stent in question. For example, a  $\Delta$  of 2 mm indicates that the circumference of the stent



1 in question was reduced by 2 mm, and the force necessary to effect that displacement was  
2 then recorded.

3 Advantages of the tapered stent of the present invention include superb flexibility,  
4 repositionability and removability, precise positionability, and better matching than a  
5 cylindrical stent with a uniform diameter between the tapered vessel and the stent which  
6 may result in less intimal reaction and longer vessel patency.

### 7 *Covered Stents*

8 Various material may be suitably used as grafts (including materials used as  
9 covers and those used as liners) that may be attached to the present woven stents so as to  
10 create stent grafts. One type of covering material that may be utilized for this purpose is  
11 made from material that is stretchable enough to substantially follow the movement of the  
12 stent's mesh. This type of graft material includes woven polyester, Dacron, polyurethane  
13 and the like. Depending on the application, the graft material may, for example, be  
14 somewhat porous (to facilitate endothelial ingrowth), highly porous (to leave bridged side  
15 branches patent) or non-porous (e.g., to exclude an aneurysm or fistula from circulation,  
16 or in another application to prevent tumor ingrowth into the stent graft lumen).

17 The graft material may be attached to either the outer or the inner surface of the  
18 stent, so as to serve as a cover or a liner, respectively. The graft material may be attached  
19 to the stent using monofilament sutures (e.g., polypropylene such as 5-0, 6-0, 7-0 Prolene,  
20 which is commercially available from Ethicon), glue, heat, or any other appropriate  
21 means.

22 Graft materials that are not stretchable or elastic may also be utilized to form stent  
23 grafts. One such material is PTFE. Such graft material may be attached to only one of  
24 the stent end's, thereby allowing free movement of the wire mesh. The attachment  
25 between the stent and the graft material may be created at the proximal end of the  
26 resulting stent graft (that is, the end of the stent that will be closest to the operator).

1           Such a stent graft may be pre-loaded into an appropriately-sized sheath. The graft  
2 material may be folded or arranged so that it occupies as little space within the sheath as  
3 possible.

4           Delivering a stent graft having a graft material made from a relatively non-  
5 stretchable material such as PTFE may be performed in a manner that is different than the  
6 manner in which a stent graft having a stretchable graft material may be delivered. For  
7 example, with a stent graft having a cover made from relatively non-stretchable graft  
8 material, after the stent graft is positioned as described below in greater detail, the sheath  
9 may be retracted and the graft material may thereby be exposed. Then the stent may be  
10 allowed to assume its unconstrained diameter by using the coaxial delivery system. The  
11 fact, that the coaxial delivery system enables to achieve a more compressed mesh  
12 tightness than that achievable by allowing the stent to recover, may be advantageous to  
13 create an adequate contact between both the stent and the graft as well as between the  
14 stent graft and the vessel wall. The different delivery mechanism requires a different  
15 approach to stent graft retrieval. First, the stent is completely restretched over the  
16 delivery tubes and the stent's completely elongated position is secured by the proximal  
17 lock mechanism. Second, the sheath is advanced preferably using some rotating  
18 movement to recapture the graft material. The creation of the attachment site between the  
19 stent and the graft at the proximal end of the stent is advantageous for possible  
20 repositioning. The stent's proximal end is secured to the outer delivery tubes, and the  
21 graft to the proximal end of the stent, therefore, the proximal portion of the graft is  
22 formed into a funnel shape facilitating its retrieval into the sheath.

### 23           *Side-By-Side Stent Placement in Aorta and Bilateral Renal Artery*

24           The present stents may be delivered in a variety of anatomical structures. Further,  
25 they may be used in conjunction with each other in a variety of manners to best treat the  
26 diseased structure. For example, as shown in FIG. 54, the bilateral aorto-renal junction  
27 830, consisting of aorta 832, left renal artery 834 and right renal artery 836, along with  
28 the aorto-iliac junction 840, consisting of left iliac artery 842 and right iliac artery 844,  
29 may be treated using uses two stents positioned in side-by-side relationship with each

1 other. Alternatively, stent grafts shorter in length than those shown in **FIG. 54** may be  
2 delivered within the aorta or the aorto-iliac junctions with some overlap therebetween.

3 The stents that may be utilized may be woven and annealed as described above on  
4 a variety of templates. In one embodiment, straight templates may be used. The stents  
5 may also be woven and annealed as described above so as to be relatively tapered, such as  
6 those in **FIG. 54**. In such a configuration, the portions of the stents that will occupy the  
7 aorta may be larger in caliber than those portions of the stents that will occupy the renal  
8 arteries. The stents may also be woven on templates that are configured with a bend that  
9 may approximate or match the angle between the appropriate renal artery and the aorta.

10 Stents that may be partially or completely provided (*i.e.*, covered or lined) with  
11 any of the graft materials described above using any of the methods of connection  
12 described above may be used in this application. In the embodiment of the pair of stents  
13 illustrated in **FIG. 55**, the portions of the stents that occupy aorta **832** and portions of the  
14 stents proximate the caudad surfaces **838** of renal arteries **834** and **836** are covered. By  
15 only partially covering the portions of the stents that will occupy renal arteries **834** and  
16 **836**, the possibility of endoleak from the renal arteries may be greatly reduced or  
17 eliminated.

18 In another possible embodiment suitable for this application illustrated in **FIG.**  
19 **56**, the aorto-renal stent may include struts **850** that may be formed by twisting  
20 neighboring segments of wires **5** during the weaving process. Struts **850** may also be  
21 formed in any suitable manner such as by encasing neighboring segments of wires **5** in  
22 flexible tubes, such as those made of nitinol, or by soldering or welding neighboring  
23 segments of wires **5** together, *etc.* As used herein, "struts" means segments of wires that  
24 are joined together in any suitable manner such as twisting, encasing within a sufficiently  
25 flexible piece of tubing, soldering, welding, *etc.*, such that the portion of the stent formed  
26 from the struts is less disruptive of the blood flow therethrough than would be the same  
27 portion formed from a weave. The stent graft having struts **850** may, like the stent grafts  
28 depicted in **FIG. 55**, be covered partially with any suitable graft material, such as those  
29 relatively stretchable materials disclosed above. Accordingly, the portions surrounding

1 struts 850 may be covered while leaving struts 850 uncovered and therefore arranged so--  
2 that when delivered as shown in FIG. 56, struts 850 are advantageously positioned within  
3 the vasculature with regard to hemodynamics. The use of struts 850 in this fashion may  
4 be advantageous in comparison to leaving a similar portion of the stent utilized simply  
5 bare, as in FIG. 55, in that struts 850 would be less likely to create turbulence in the  
6 blood flow.

7 In one embodiment of the stent graft illustrated in FIG. 56 having struts 850,  
8 different portions of the stent may be provided with different numbers of wires. Turning  
9 to such a stent, the weave may begin at the end of the stent that will be placed in the renal  
10 artery and made be made from  $n$  wires. The portion of the stent occupied by struts 850  
11 may also be made from  $n$  wires. The larger portion of the stent that will occupy the aorta  
12 may use  $n+x$  wires, where  $x$  denotes the number of additional wires utilized, and may be  
13 between 1 and  $2n$ . Preferably,  $x$  is selected from an integer between 2 and  $n$ , and more  
14 preferably  $x$  equals  $n$ . The template on which this type of stent is formed may have pins  
15 304 positioned, for example, at locations proximate the end and beginning of struts 850.

#### 16 *Biodegradable Devices*

17 Both the straight and the tapered stents of the present invention (as well as the  
18 filters and occluders discussed below), except for the single wire embodiments of these  
19 devices, may be formed with filaments made of biodegradable material so as to form self-  
20 expanding, bioabsorbable, biodegradable stents that may, in addition to functioning as  
21 stents, function as drug or nutrient delivery systems as a result of the material used.

22 Many factors may be considered in choosing materials from which to form the  
23 biodegradable stents of the present invention. In one embodiment, the biodegradable  
24 stents of the present invention may be formed from materials of minimal thickness so as  
25 to minimize blood flow blockage and facilitate bioabsorbtion. In another embodiment,  
26 the material may be chosen so as to exhibit sufficient radial strength to allow the body  
27 formed to function as a stent. The material from which the biodegradable stents may be  
28 formed may also degrade within the bloodstream over a period of weeks or months, so as

1 not to form emboli. The material may be chosen such that the stent does not degrade  
2 before an endothelial layer forms in the stented vessel or structure in cases in which  
3 stenosed aortoiliac arteries with lengthy affected segments are treated. The material  
4 chosen may be chosen to be compatible with surrounding tissue in the vessel as well as  
5 with blood.

6 The body of a biodegradable stent may be formed by plain weave using the  
7 methods above described. The size of the filaments used may vary according to the  
8 application. In some embodiments, the filaments may be reduced in size in comparison  
9 to the size of wires used in comparable applications involving non-biodegradable devices.  
10 In other embodiments, the number of filaments used may be increased in comparison to  
11 the number of wires used in comparable applications involving non-biodegradable  
12 devices.

13 The minimum number of filaments that may be used to create the body of a  
14 biodegradable device (including stents, occluders and filters) may be about 5. In one  
15 embodiment, 12 filaments may be used. With regard to stents, in creating the body using  
16 plain weave, the angle of the crossed filaments (described above as angle  $\alpha$ ) may vary as  
17 described above, but is typically 150-160°. In one embodiment, the angle of the crossed  
18 filaments may be as large as possible to achieve the largest radial force possible and  
19 further ensure that the stent may have enough expansile force to remain in place after  
20 being delivered. The filament ends, after plain weaving is complete, may be coupled  
21 together to form closed structures using any suitable means such as by heat treatment or  
22 sealing, gluing, tying, twisting, crimping, taping, or the like. In another embodiment, a  
23 long body may be woven, and the body may be cut into tubular segments. Closed  
24 structures may be formed at both ends of the segmented bodies by coupling the filament  
25 ends together as above described.

26 In one embodiment, the filaments used may be made of polyglycolic acid  
27 ("PGA"), poly-L-lactic acid ("L-PLA"), polyorthoesters, polyanhydrides,  
28 polyiminocarbonates, or inorganic phosphates. These polymers are commercially  
29 available from United States Surgical Corporation, Norwalk, CT; Birmingham Polymers,

1 Inc., Birmingham, AL; and Ethicon, Sommerville, NJ, for example. One factor to  
2 consider in choosing a material from which to make the filament will be the goal of the  
3 stent placement. For example, in an embodiment in which the stent serves mainly as a  
4 drug delivery system, PLA may be used because of its rapid degradation time. In another  
5 embodiment in which the stent serves mainly to maintain the patency of the vessel (*i.e.*,  
6 keeping the vessel open) and as a scaffold or frame for the development of a new  
7 endothelial layer, PGA may be used considering its high strength and stiffness. In other  
8 embodiments, glycolide may be copolymerized with other monomers to reduce the  
9 stiffness of the resulting fibers that may be used.

10 In another embodiment, any of these filaments may be provided with about 0.05  
11 to 0.25 percent by weight of a basic metal compound, such as calcium oxide, calcium  
12 hydroxide, calcium carbonate, calcium phosphate, magnesium oxide, magnesium  
13 hydroxide, magnesium carbonate, magnesium phosphate, sodium phosphate, potassium  
14 sulfate or the like, to increase the *in vivo* strength retention of the biodegradable stent by  
15 about ten to twenty percent or more, as described in U.S. Patent No. 5,478,355 to Muth  
16 *et al.* (1995), which is hereby expressly incorporated by reference. As used herein, "*in*  
17 *vivo* strength retention" refers to the ability of a biodegradable body to retain its strength  
18 (*i.e.*, the breaking load of the body) after being implanted or delivered into a living  
19 creature. In yet another embodiment, a filament obtained from a polymer containing  
20 about 15 to about 30 mole percent glycolide in a melt spinning operation, as described in  
21 U.S. Patent No. 5,425,984 to Kennedy *et al.* (1995), which is hereby expressly  
22 incorporated by reference, may be used to form a biodegradable body.

23 The filaments of the biodegradable devices may incorporate one or more drugs  
24 that positively affect healing at the location where the stent is delivered. In one  
25 embodiment, these drugs may include anticancer drugs such as paclitaxel (which is  
26 commercially available as TAXOL, from Bristol-Myers Squibb in Princeton, NJ) or  
27 docetaxel (which is commercially available as TAXOTERE, from Phone-Poulenc Rorer  
28 in Collegeville, PA), fibroblast/smooth muscle cell proliferation-preventing agents, and

1 antithrombogenic drugs such as heparin which is commercially available from Wyeth-  
2 Ayers in Philadelphia, PA.

3 One or more drugs may be incorporated into a polymer using any suitable means.  
4 For example, in one embodiment, the drugs as a solute may be dissolved in the  
5 biodegradable polymer as a solvent to form a solution. The solution may then be  
6 hardened into a fiber from which the stent may be woven. In another embodiment,  
7 simple mixing or solubilizing with polymer solutions may be utilized. The drugs may  
8 also be dispersed into the biodegradable polymer during an extrusion or melt spinning  
9 process. In yet another embodiment, the biodegradable fibers that have already been  
10 formed may be coated with drugs.

11 The biodegradable filaments may be rendered radiopaque to facilitate their  
12 monitoring under fluoroscopy and/or their follow-up using radiographs, fluoroscopy, or  
13 computerized tomography. The methods described above for incorporating the drugs into  
14 the polymer may be used to mix radiopaque salts, such as tantalum, with the polymer.

15 As used herein, "degradation time" refers to the time during which the  
16 biodegradable device maintains its mechanical integrity. One factor that should be  
17 considered in choosing a polymer in light of its degradation time is that the polymer will  
18 lose its mechanical integrity before it is completely absorbed into the body. For  
19 example, pure polyglycolide (PGA) sutures lose about 50% of their strength after 2  
20 weeks, and 100% at 4 weeks, and are completely absorbed in 4-6 months. For vascular  
21 applications (*i.e.*, applications in which the stent is placed within a vessel in a body),  
22 polymers having degradation times of about one to twenty-four months may be used,  
23 depending on the application. In a typical embodiment, a polymer having a degradation  
24 time of about one to three months may be used. In choosing a polymer for non-vascular  
25 applications such as the esophagus, colon, biliary tree, ureter, *etc.*, one should consider  
26 the polymer's ability to withstand the chemical stimuli in the given environment.

27 During the degradation time of a biodegradable stent, a new endothelial layer may  
28 form on the surface of the stent. The rate of the release of the drugs which may be

1 incorporated into the polymers may be controlled by the rate of degradation of the  
2 biodegradable material used. Thus, the rate of release of a drug may act as a control  
3 quantity for the rate of degradation. At the same time, other agents such as fibronectin  
4 from human plasma (commercially available from Sigma, St. Louis, MO) may be added  
5 to the polymer used (using any suitable means described above for incorporating drugs  
6 into the chosen polymer) and may affect the rate of biodegradation. For example,  
7 fibronectin may accelerate the growth of cells around the surrounding stent, which, in  
8 turn may accelerate the resorption reactions around the stent.

9 In one embodiment of a biodegradable body according to the present invention,  
10 one or more shape memory wires may be added to the body for reinforcement after it is  
11 formed using plain weave. Such wires may comprise nitinol or any other comparable  
12 material above described. In one embodiment, the wires may be formed from nitinol  
13 having about 55 to 56% Nickel and 45 to 44% Titanium (Shape Memory Applications).  
14 The wire or wires may be incorporated into the woven biodegradable body by threading  
15 the wire in and out of openings in the body several times. In one embodiment, the  
16 manner in which the wire is threaded in and out of openings in the body is shown in  
17 **FIG. 31**. In **FIG. 31**, designation **520** shows reinforcement wire **510** passing outside  
18 biodegradable body **500**, and designation **530** shows reinforcement wire **510** passing  
19 inside biodegradable body **500**, thus showing how wire **510** may be threaded in and out of  
20 openings in body **500**. As shown in **FIG. 31**, the reinforcement wire(s) **510** may be led  
21 between (*i.e.*, parallel to) two biodegradable filaments **540** and may follow their helical  
22 course. As shown in **FIG. 31**, reinforcement wire **510** may be secured to body **500** with  
23 loops **550**, or any other suitable means such as tying, twisting, or the like. Loops **550** may  
24 be placed around a filament or around the intersection of one or more filaments. As a  
25 result, the wire can move in harmony with the weave and will not interfere with the  
26 movement of the filaments in the weave. By activating the superelasticity or thermal  
27 shape memory of reinforcement wire **510**, ends **560** and **570** of body **500** may be pulled  
28 together, resulting in a tighter weave. As a result, the expansile force of the stent and its  
29 resistance to outer compression may significantly increase. In one embodiment, loops  
30 **550** may also be used in securing body **500** to a delivery system.



1 In another embodiment shown in FIG. 32, in which a reinforcement wire is  
2 threaded in and out of openings in a biodegradable body according to the present  
3 invention, reinforcement wire 510 may be bent at a selected point located between its  
4 ends, typically at about the mid-point of the wire, and a small loop 512 may be created  
5 (similar to the small closed loops described above). As shown in FIG. 32, small loop 512  
6 may be entwined around a filament or the intersection of one or more filaments, and  
7 reinforcement wire 510 may be threaded in and out of the openings in body 500 as  
8 described above, and may be secured to body 500 with loops 550, or any other suitable  
9 mean, as above described. Both portions 514 of reinforcement wire 510 may be  
10 symmetrically led along both sides of body 500 following the sinuous/helical course of  
11 the biodegradable filaments. As described earlier, by activating the superelasticity or  
12 thermal shape memory of reinforcement wire 510, ends 560 and 570 of body 500 may be  
13 pulled together, resulting in a tighter weave. As a result, the expansile force of the stent  
14 and its resistance to outer compression may significantly increase. In one embodiment,  
15 loops 550 may also be used in securing body 500 to a delivery system.

16 In one embodiment, the size of reinforcement wire 510 may range from about  
17 0.005 inches to about 0.012 inches. It is to be understood that increasing the size of  
18 reinforcement wire 510 may increase the force with which ends 560 and 570 are pulled  
19 together when the shape memory of the wire is activated. It is to be understood that using  
20 more than one wire may have the same effect as increasing the size of the wire.

21 In one embodiment, reinforcement wire(s) 510 may be formed around a template  
22 as above described. The reinforcement wire(s) may then be programmed with  
23 superelasticity or shape memory as described herein.

#### 24 *Bench-work*

25 With regard to the biodegradable version of the stents according to the present  
26 invention, the inventors have used an open-ended plain woven nylon body (that is, the  
27 filament ends were not coupled together to form closed structures after weaving) for  
28 initial bench work. The tubular body was woven using 0.007 inch nylon filaments. The

1 number of filaments used was 16, and the unconstrained diameter of the tube was 11 mm.  
2 In an unconstrained state, the size of the weave holes was approximately 1 mm. The  
3 expansile force of the tube was relatively good, and after maximum elongation the tube  
4 readily reverted to its unconstrained diameter. Compressing the tube from its two ends  
5 longitudinally, the expansile force could be increased considerably. At the maximal  
6 longitudinal compression, the diameter of the tubular mesh was 13 mm. Holding both  
7 ends of the tube, the stent became virtually incompressible.

8 A 0.006" nitinol wire was threaded through the holes of the unconstrained mesh in  
9 the manner described earlier. The wire was a straight nitinol wire and was not formed on  
10 a template and programmed with either shape memory or superelasticity. The straight  
11 wire caused the mesh to elongate and the unconstrained diameter of the tube decreased to  
12 9.5 mm (13% lumen-loss) though the other characteristics of the mesh did not change.  
13 The woven tubular structure could be elongated completely as well as compressed  
14 maximally.

## 15 1.5 Occluders

16 With reference to the illustrative embodiments shown in FIGS. 33A-G, 34, and  
17 35, there are shown occluders for insertion and delivery into an anatomical structure. An  
18 occluder according to the present invention may be used to substantially or completely  
19 prevent the flow of blood through a vessel. Body 700 of the occluder may be formed  
20 using plain weave by the methods above described. The types of structures into which an  
21 occluder according to the present invention may be placed include arteries, veins, patent  
22 ductus arteriosus, and the ureter.

23 In one embodiment of the present invention, an occluder may be formed by  
24 weaving a body for use as a stent as above described. The body may then be heated and  
25 allowed to cool as above described. The body may then be remodeled (*i.e.*, mounted on  
26 another template in a manner similar to the manner in which the body was coupled to the  
27 first template (*e.g.*, using a copper support wire)), and reheated and cooled in a manner  
28 similar to the original heating and cooling. The template that may be used in the

1 remodeling may have the desired shape of the occluder in one embodiment. In another  
2 embodiment, a tubular template, preferably with a smaller caliber than that of the original  
3 template, may be used. In this embodiment, after securing one end of the body to the  
4 template using support wire or any other suitable means, the distance between the two  
5 ends of the body may be appropriately decreased. As a result, the mid-portion of the body  
6 will balloon outward (FIG. 33B). Depending on the distance between the two ends of the  
7 body, a series of different shapes may be created. The shapes may include a round shape  
8 (FIG. 33A), an elongated fusiform shape (FIG. 33B), a compressed fusiform shape  
9 (FIG. 33C), a compressed fusiform shape with an inverted distal end (FIG. 33D), a flat  
10 disc configuration (FIG. 33E), a shape in which the proximal end of the occluder is  
11 inverted into the body of the occluder (FIG. 33F), a torpedo shape (FIG. 33G), etc. After  
12 achieving the desired shape of the body, the other end of the body may also be secured to  
13 the template. The body/template unit may then be heated and cooled again. The heating  
14 temperatures and times disclosed above may be utilized.

15 To increase the thrombogenicity of the occluder, (i.e., the ability of the occluder to  
16 prevent the flow of fluid) thrombogenic materials in the form of an occluding agent may  
17 be enclosed within the body. Any suitable material may be used for the occluding agent.  
18 The size and shape of the occluding agent may be varied according to need. In one  
19 embodiment, one or more threads of polyester may be used as an occluding agent. The  
20 threads may be coupled to the body at one or both of the ends of the body using any  
21 suitable means such as sutures. The threads may also be placed loosely within the body.  
22 In another embodiment, DACRON threads may be used as an occluding agent. The  
23 DACRON may be coupled to the body at one or both ends of the body using any suitable  
24 means such as monofilament sutures, glue, or the like. The DACRON may also be  
25 placed loosely within the body.

26 In one embodiment of the present invention, a stretchable jacket may be  
27 configured to cover at least a portion of the body of an occluder (FIG. 34). Any suitable  
28 material may be used for the jacket. In one embodiment, the jacket may be made of  
29 polyurethane. In another embodiment, the jacket may be made of silicone. The jacket

1 may have a thickness of about 0.02 mm, but it will be understood that any suitable  
2 thickness may be substituted therefor. The jacket may be coupled to either the inner or  
3 outer surface of the body using glue, heat, or any other suitable means. In one  
4 embodiment, by coupling the jacket to the outer surface of the body, the body may be  
5 easily manipulated within a hollow covering such as a sheath during the insertion and  
6 delivery of the occluder.

7 The closed structures of the ends of the body used as the occluder may be held  
8 together using any suitable means. In one embodiment, a monofilament suture  
9 (polypropylene, Prolene 5-0, 6-0, 7-0, from Ethicon) may be used to hold the closed  
10 structures of the body together by threading the suture through the closed structures or  
11 other nearby openings. In another embodiment, metal clips 710 may be used to hold the  
12 closed structures of the body together (FIG. 35). In holding the closed structures  
13 together, in one embodiment, the closed structures may be held together such that the  
14 tubes of the delivery system (described in detail below) may easily pass through the  
15 lumen of the occluder. In another embodiment, the closed structures of the ends of the  
16 body may not be held together.

17 During deployment of such as occluder, the interventionalist is always able to  
18 correct any misplacement by simply restretching the wire mesh and repositioning the  
19 body using the delivery system. Even after the distal end of the occluder has been  
20 released, the proximal end still remains attached to the delivery system offering another  
21 safety feature for removal of the occluder.

22 The single wire embodiment may also be utilized as a structure for causing vessel  
23 occlusion. Such an occluder should have at least two loops. FIGS. 57A-D illustrate  
24 various single wire embodiment occluders. FIG. 57A illustrates body 700 on template  
25 300 after having been formed thereon using, for example, either the hand weave or  
26 machine weave method described above. As shown, body 700 of the occluder has 3  
27 loops. At this stage of the development of the occluder illustrated in FIG. 57A, body 700  
28 is simply a single wire embodiment stent.

1           After the body/template unit has been annealed using, for example, the annealing  
2 method described above for imparting body 700 with superelastic properties, body 700  
3 may be removed from template 300. Body 700 may then be stretched by pulling the two  
4 ends thereof longitudinally apart, and collars 702 may be slipped over either end and  
5 placed at the locations where first segment 704 and second segment 706 cross each other.  
6 Collars 702 may be small pieces of metal, such as small pieces of a nitinol tube  
7 (commercially available from Shape Memory Applications, Santa Clara, CA). In doing  
8 this, segments 704 and 706 extend between the loop-defining locations hidden by collars  
9 702 so as to form loops 710. A collar 702 may also be placed around the ends of the wire  
10 forming body 700. At the loop-defining locations, which are hidden by collars 702,  
11 segments 704 and 706 may be positioned adjacent to each other. As used herein,  
12 segments that are "adjacent" to each other may or may not touch each other, but such  
13 segments are positioned in close proximity to each other such that the distance separating  
14 them is generally no more than about 1 mm. The length of the wire segments covered by  
15 collars 702 should be sufficiently short so as not to impede the flexibility of the single  
16 wire embodiment occluder.

17           Although not shown, it will be understood to those of skill in the art, with the  
18 benefit of this disclosure, that any suitable means may be used to secure segments 704  
19 and 706 adjacent to each other in the loop-defining locations. Such means include  
20 wrapping the segments together with any suitable wire, crimping a piece of metal around  
21 the segments, welding the segments together, and the like.

22           With collars 702 in place, the shapes of loops 710 are altered such that loops 710  
23 possess generally compressed shapes. As shown in FIG. 57B, the two largest of the three  
24 loops 710 have fairly pronounced compressed shapes relative to the smallest loop 710.  
25 The compressed shape may exaggerated (*i.e.*, made more compressed) by decreasing the  
26 distance between collars. Laterally pulling the portions of segments forming a given loop  
27 apart may be done to alter the distance between collars. The collars should maintain the  
28 shapes of the loops and thereby stabilize the occluder within the anatomical structure into  
29 which it is delivered. However, the collars may be crimped to further improve their

1 ability to maintain the shapes of the loops. In this same regard, body 700 may be secured  
2 to a template having a suitable shape and re-annealed so that the compressed shapes of  
3 loops 710 are maintained. Further, re-annealing body 700 may improve the expansile  
4 force and resulting self-anchoring capability of the single wire embodiment occluder.

5 The number of loops utilized to form a single wire embodiment occluder may be  
6 reasonably increased. For example, an occluder formed using the single wire  
7 embodiment may have 3, 4, 5, 6 or more loops.

8 The shape of the loops of the single wire embodiment occluders may be varied as  
9 desired to best cover the cross-section of the anatomical structure to be occluded in a  
10 manner that will likely cause occlusion in the most rapid manner possible. Accordingly, a  
11 single wire embodiment occluder may have loops that possess differing sizes, such as an  
12 occluder having one or more loops near one end that are smaller than one or more loops  
13 near the other end of the occluder. As used herein, the total length of the segments that  
14 define a loop that is "smaller" than another loop of a single wire embodiment is less than  
15 the total length of the segments that define the larger loop. In another embodiment, the  
16 occluder may appear tapered, where the loops decrease in size from one end to the other.  
17 In another alternative embodiment, one or two small loops may be arranged at or near the  
18 mid-portion of a single wire embodiment occluder, while the loops at the proximal and  
19 distal ends may be larger by comparison and possibly equal to each other in terms of size.

20 In order to increase the thrombogenicity of the single wire embodiment occluders,  
21 various occluding agents may be attached to the occluder. Any suitable material may be  
22 used for the occluding agent. For example, pieces of a metal coil, such as one made from  
23 stainless steel, may be pulled over the wire segments prior to slipping collars over them.  
24 In this regard, the single wire embodiment occluder may be re-annealed as described  
25 above, the collars may be removed, the coil pieces may be placed over the segments, and  
26 the collars may be replaced at the loop-defining locations. As illustrated in FIG. 57C,  
27 coil pieces 714 are placed over the segments between collars 702. The coil pieces may  
28 also be wires, such as stainless steel or nitinol wires, that are manually wrapped around

1 the segments and attached to the segments in any suitable fashion. The coil pieces may  
2 be pre-formed hollow pieces of coil made from any suitable metal or alloy.

3 Thrombogenic filaments (such as polyester fibers) may also be attached to coil  
4 pieces 714 to further increase the thrombogenicity of the single wire embodiment  
5 occluders. As illustrated in FIG. 57D, polyester fibers 716 are attached to coil pieces 714  
6 at various locations along the coil pieces. The length of the thrombogenic filaments may  
7 vary, as may the distance between the filaments, in order to ensure that the resulting  
8 thrombogenicity of the single wire embodiment occluder is best-suited to the application.  
9 The thrombogenic filaments may be individual fibers or bundles of fibers.

10 In another embodiment, segments of the single wire embodiment occluder may be  
11 covered by bundles of thrombogenic filaments, such as filaments made of polyester, such  
12 that the bundles resemble the coil pieces, and additional thrombogenic filaments, such as  
13 polyester fibers, may be attached to or braided with the bundles of filaments such that  
14 they extend away from the covered segments in the same fashion as fibers 716 illustrated  
15 in FIG. 57D.

#### 16 *Delivery Systems for Stents, Stent Grafts and Occluders*

17 With reference to FIG. 3, the delivery system 20 for body 10, tapered body 100  
18 and body 700 (including biodegradable versions thereof), may consist of two flexible  
19 tubes arranged coaxially. These tubes may be formed of material such as TEFLON or  
20 NYLON, which are commercially available from Cook, Inc. (Bloomington, IN), or other  
21 similarly suitable materials. It is to be understood that material that is less flexible or  
22 firmer than TEFLON may also be used. Further, it is to be understood that material with  
23 a thinner wall thickness than that of TEFLON tubing, such as the material from which the  
24 WALLSTENT delivery system is formed, may be utilized. In one embodiment, one or  
25 both tubes may be made of metal, such as nitinol, which is commercially available from  
26 Shape Memory Applications. Nitinol tubes may be particularly well-suited for use in  
27 delivery systems that are relatively large or rigid, such as for tracheal or bronchial  
28 stenting.

1           The size of the outer diameter of the distal, small caliber tube 22 may range from  
2   2.5 to 7.5 French ("F") depending on the application of the stent, the size of the stent, and  
3   the number of securing wires (to be discussed below) that may be used to secure the stent  
4   to tube 22 (to be discussed below). For coronary applications, for example, the size of  
5   tube 22 may be about 3-F. For delivery of a medium stent into the renal or carotid  
6   arteries, for example, the size of tube 22 may be about 5-F. The length of tube 22 may  
7   range from 80 cm to about 120 cm depending on the application of the stent and the size  
8   of the stent. In an exemplary embodiment, for example, for delivery of an iliac artery  
9   stent from a contralateral approach, the length of the tubing may be about 90 cm. In  
10   another exemplary embodiment, for carotid artery stenting, the length of the tubing may  
11   be about 110 cm. The size of the stent may also have affect the length of tube 22. Thus,  
12   in an exemplary embodiment, the larger the stent diameter, the longer the stent is in its  
13   completely elongated state.

14           Tube 22 as well as tube 40 (discussed below) may be provided with a flange or  
15   hub near its proximal end so as to allow for control of the position of tube 22 during  
16   delivery of the stent. In an exemplary embodiment as shown in FIG. 25, a push button  
17   lock/release mechanism 200 (such as a FloSwitch®HP device from Meditech/Boston  
18   Scientific Corp., Watertown, MA or a CRICKETT device from Microvena in White Bear  
19   Lake, MN) may be utilized for securing tube 40 to tube 22 when necessary. As further  
20   illustrated in FIG. 25, an end fitting 204 with a side arm may be utilized with a Luer-lock  
21   mechanism and/or tightening screws for further facilitating delivery of the stent.  
22   Although not shown, it will be understood by those of skill in the art, with the benefit of  
23   this disclosure, that the hub or flange that may be provided on the end of tube 22 may be  
24   used to facilitate the connection between end fitting 204 and tube 22. Similarly, although  
25   not shown, it will be understood by those of skill in the art, with the benefit of this  
26   disclosure, that the end of tube 40 may be provided with a hub or flange that may be used  
27   to facilitate the connection between push button lock/release mechanism 200 and tube 40.  
28   End fitting 204 may be equipped with separated lumens in a double channel system. One  
29   or more steerable guidewires 203 may be utilized in the lumen of tube 22 and in the  
30   lumen of end fitting 204 for facilitating delivery of the devices described herein.



1           It is to be understood that radiopaque markers may be placed on tube 22 at  
2 appropriate locations in a manner known in the art in order to better enable viewing of  
3 tube 22 using fluoroscopy during delivery of the stent.

4           As shown in FIG. 3, the distal, smaller caliber tube 22 is equipped with proximal  
5 hole 24 and distal hole 26. Distal hole 26 may be typically located between about 0.5 and  
6 about 3.0 cm from distal end 28 of tube 22, most typically about 1 cm. The location of  
7 the radiopaque markers on tube 22 may affect this distance. The distance between holes  
8 24 and 26 may be typically about 3 to 8 mm, but most typically about 3 to 5 mm. This  
9 distance may be affected by the size of the securing wire 30. For example, the distance  
10 between the holes may decrease as the diameter of wire 30 decreases.

11           Securing wire 30 may be placed within the lumen of tube 22 (the dotted line  
12 indicates that securing wire 30 is located within tube 22), and may pass through holes 24  
13 and 26 so as to form a small-profile, tight securing loop 32 between the two holes. Distal  
14 end 34 of securing wire 30 terminates at or near distal end 28 of tube 22. Proximal end of  
15 securing wire 30 may be connected to a handle 206 as shown in FIG. 25.

16           Securing loop 32 holds the small loops (6 and 106) or bends (8 and 108) of distal  
17 end (12 or 102) of body 10 or tapered body 100 in position during delivery (delivery  
18 being described in more detail below.) Advantageously, securing loop 32 also prevents  
19 premature delivery of the stent. Thus, prior to delivery of the stent, distal end 34 of  
20 securing wire 30 passes out through proximal hole 24, passes through the small loops or  
21 bends of the stent, and passes back into the lumen of tube 22 through distal hole 26,  
22 terminating prior to distal end 28, thus securing the distal end of the stent to tube 22. It is  
23 to be understood that securing wire 30 may pass through one of the openings in the plain  
24 weave of body 10 or tapered body 100 other than the small loop (6 and 106) or bend (8  
25 and 108).

26           In most applications, securing wire 30 ranges in size from about 0.006 inches to  
27 about 0.011 inches in diameter. However, the size of securing wire 30 in any given  
28 application depends upon several factors. For example, a larger (in terms of diameter)

1     securing wire provides more resistance to the propensity of a stretched stent to contract.  
2     than does a smaller wire. Additionally, when more than one securing wire is utilized, the  
3     size of the wires can be less than if only one securing wire were used. The securing wires  
4     of the present invention may be made of any of the shape memory materials described  
5     above. In one embodiment, the securing wires of the present invention are made of  
6     nitinol. In another embodiment, the securing wires of the present invention may be  
7     formed of nitinol having about 55 to 56 % Nickel and about 45 to 44 % Titanium  
8     (commmercially available from Shape Memory Applications). In an embodiment in which  
9     the securing wires of the present invention are nitinol (including wires 30 and 46,  
10    discussed below), the nitinol securing wires may be heat treated as described herein or  
11    purchased from a manufacturer such that the superelastic properties of the nitinol may be  
12    utilized.

13         The proximal, larger caliber tube 40 is also equipped with proximal and distal  
14    holes 42 and 44 typically located in approximately the same location from distal end 41  
15    of tube 40 as are holes 24 and 26 from distal end 28 of tube 22. The distance between  
16    holes 42 and 44 is also comparable to the distance between the holes in tube 22.

17         The size of the outer diameter of the proximal tube 40 may range from about 4.5-  
18    F to about 10-F depending on the application of the stent, the size of the stent, and the  
19    number of securing wires that may be used to secure the proximal end of the stent to tube  
20    40 (to be discussed below). For coronary applications, for example, the size of tube 40  
21    may be about 5-F. In an exemplary embodiment, for carotid artery stenting, the size of  
22    tube 40 may be about 7 to about 8-F. The length of tube 40 may range from about 70 cm  
23    to about 110 cm depending on the application of the stent and the size of the stent. In an  
24    exemplary embodiment, the length of tube 40 may typically be about 10 cm to about 20  
25    cm shorter than the length of tube 22. It is to be understood that the proximal end of  
26    tube 22 may extend beyond the proximal end of tube 40, just as distal end 28 of tube 22  
27    extends beyond distal end 41 of tube 40 as shown in FIG. 3. In an exemplary  
28    embodiment, the factor that may primarily influence the length of the delivery system  
29    (i.e., tubes 22 and 40) is the distance of the stented region from the access site (typically

1 the femoral artery). As with tube 22, tube 40 may be provided with a flange or hub near  
2 its proximal end so as to allow for control of the position of tube 40 during delivery of the  
3 stent.

4 It is to be understood that radiopaque markers may be placed on tube 40 at  
5 appropriate locations in a manner known in the art in order to better enable viewing of  
6 tube 40 using fluoroscopy during delivery of the stent.

7 Securing wire 46 is positioned with the lumen of tube 40, and forms small-profile,  
8 tight securing loop 48 in the manner above described. Securing loop 48 holds closed  
9 structures (4 and 104) of proximal end (2 and 112) of body 10 and tapered body 100 in  
10 position during delivery, and advantageously prevents premature delivery of the stent. It  
11 is to be understood that securing wire 46 may pass through one of the openings of the  
12 plain weave of body 10 or tapered body 100 other than the closed structures. The closed  
13 structures are secured using the manner described above for the loops or bends.

14 Securing wire 46 and securing wire 30 may be formed from the same materials as  
15 the wires making up the stent. Additionally, securing wire 46 may be approximately the  
16 same size as securing wire 30, and the same types of factors discussed above should be  
17 considered in sizing securing wire 46.

18 In FIG. 3, although only one securing loop is shown on either tube, it is to be  
19 understood that more than one securing loop may be utilized on each tube to secure the  
20 proximal and distal ends of the stent. More securing loops may be achieved with the  
21 same securing wire, or by using more securing wires. As discussed above, the number of  
22 securing wires that may be used may depend on several factors, such as the amount of  
23 force needed to elongate or constrain the stent prior to delivery. For example, the more  
24 resistant the stent is to elongation, the more securing wires may be used in order to  
25 facilitate the stretching or elongation of the stent on the delivery system. By this means,  
26 the ends of the stent can be suspended evenly around the tubes and the friction between  
27 tubes and the profile of the elongated stent can be reasonably decreased. An additional  
28 factor affecting the number of securing wires may be the use of a guidewire (described

1 below). In an exemplary embodiment of the delivery system according to the present  
2 invention, a guidewire may be utilized during delivery (described below). As a result, the  
3 use of a guidewire will affect the amount of space within tube 22 available for the use of  
4 the securing wire or wires. It is also to be understood that securing wires having tapered  
5 distal ends may be used no matter how many securing wires are used.

6 Body 700 may be secured to the delivery systems of the present invention the  
7 delivery system depicted in FIG. 3, in the same manner in which body 10 and tapered  
8 body 100 may be secured to these delivery systems as above described. In one  
9 embodiment in which the ends of body 700 are secured to tubes 22 and 40, one small-  
10 profile, tight securing loop may be used to secure each end.

11 With reference to another illustrative embodiment of the delivery system  
12 according to the present invention shown in FIG. 4, delivery system 50 has tube 22  
13 equipped with proximal and distal holes 24 and 26 in the manner above described. As  
14 shown, delivery system 50 may consist of thin-walled sheath 52 arranged coaxially with  
15 tube 22. Sheath 52 may be formed of materials comparable to those from which tubes 22  
16 and 40 are formed. Sheath 52 may be about 1 cm to about 2.5 cm in length, but typically  
17 about 1.5 cm. The distal end 54 of sheath 52 is connected or attached to tube 22 by  
18 gluing, melting, heating or any other suitable means at a location typically between about  
19 8 cm to about 20 cm from distal end 28 of tube 22, but most typically about 15 cm.

20 As shown in FIG. 4, delivery system 50 may consist of inverse tabs 60 which are  
21 connected to or engaged with the distal end of tube 40. Inverse tabs 60 are connected to  
22 or engaged with tube 40 by any suitable means, including the use of a metal ring friction  
23 fitted around tube 40, to which tabs 60 may be soldered, welded, or integrally formed.  
24 Inverse tabs 60 are connected or engaged with tube 40 at a location that may be  
25 determined based on the completely stretched length of the stent. Inverse tabs 60 may be  
26 made of any suitable material, including those from which the wires of the stent may be  
27 made, and further including stainless steel and other similar materials.

1           The following description applies to both body 10 and tapered body 100.  
2           However, reference is made only to body 10 by way of example. Inverse tabs 60 secure  
3           proximal end 2 of body 10 in the following general manner. Inverse tabs 60 are placed  
4           within the lumen of body 10. Proximal ends 62 of inverse tabs 60 are then "threaded"  
5           through closed structures 4 or other holes located near the proximal end 2 of body 10.  
6           Tube 40 is then moved in a proximal direction until closed structures 4 (or other holes)  
7           are secured by the inverse tabs. The space created between sheath 52 and tube 22 may be  
8           used to house inverse tabs 60 as below described.

### 9                           *Delivery of the Stents, Stent Grafts and Occluders*

10           Body 10 and tapered body 100 (including biodegradable versions thereof), and  
11           body 700 may be delivered in a similar manner. Thus, the following description of  
12           methods of delivery for the stents and occluders references only body 10 by way of  
13           example.

14           Prior to delivery, a stent in the form of body 10 may be manually secured to tubes  
15           22 and 40. This may be accomplished by using either securing loops in the manner  
16           described above with reference to FIG. 3 (hereinafter "version 1"), or by securing loop 32  
17           and inverse tabs 60 in the manner described above with reference to FIG. 4 (hereinafter  
18           "version 2").

19           In either version, a stent is first stretched so as to reduce its diameter by an amount  
20           appropriate to allow delivery to occur. Thus, the stent may be stretched maximally or just  
21           to an extent such that it may be inserted into a vessel or non-vascular structure, and may  
22           pass through the lumen of the vessel or non-vascular structure as the stent is being  
23           positioned prior to being delivered into the vessel or non-vascular tubular structure.  
24           When delivering the single wire embodiment discussed above, it should be noted that the  
25           ratio of the constrained length of the body to the unconstrained length of the body may be  
26           significantly greater in this embodiment than in the embodiments that utilize multiple  
27           wires. Therefore, the single wire embodiment may require a greater length within the

1 vessel or non-vascular structure in which to be manipulated and prepared for delivery  
2 than may other embodiments that utilize multiple wires.

3 The stent to be delivered may be stretched by increasing the distance between the  
4 distal ends of tubes 22 and 40. This may be accomplished by moving or sliding tube 40  
5 in a proximal direction over tube 22 while holding tube 22 stationary, or by moving or  
6 sliding tube 22 in a distal direction while holding tube 40 stationary, or by moving or  
7 sliding the tubes in the aforementioned directions simultaneously. Once the stent has  
8 been appropriately stretched, tubes 22 and 40 may be locked together in a manner well  
9 known in the art, such as with the use of tightening screws or push button mechanisms  
10 which are easily lockable and unlockable. If version 2 is used, an outer sheath 70 as  
11 shown in FIG. 5A may be used to cover inverse tabs 60.

12 In an illustrative embodiment, it is preferable to use a guidewire placed through  
13 the lumen of tube 22 for use in guiding the stent to its proper location in a manner well  
14 known in the art. The guidewire may be formed of any material from which the wires  
15 forming the stent may be made. The guidewire may be between about 0.014 inches and  
16 about 0.035 inches in diameter. In one embodiment, the guidewire may be made of  
17 nitinol (commercially available from Microvena). In another illustrative embodiment, a  
18 hollow covering such as a sheath may be placed over a stent secured to tubes 22 and 40 so  
19 as to prevent contact between the stent and the vessel or non-vascular structure during  
20 delivery of the stent.

21 The first step of inserting either delivery system into the body is to establish an  
22 access (arterial or venous). After puncturing the vessel using an adequate needle, a  
23 guidewire is inserted into the body. The needle is removed, and over the guidewire an  
24 introducer sheath with a check-flow adapter and preferably with a side-port is advanced.  
25 The guidewire is then removed. This introducer sheath, the size of which is determined  
26 by the size of the delivery system to be used, serves as an access for the intervention.

27 In version 1, when the stent, still stretched on delivery system 20, is positioned in  
28 the desired location of the vessel or non-vascular tubular structure to be stented, the

1 sheath covering the stent may be withdrawn, and the tubes may be unlocked. The stent  
2 may be positioned and then shortened so as to achieve its unconstrained diameter in a  
3 variety of manners. In an exemplary embodiment, the distal end of the stent may be  
4 positioned in its final location prior to shortening the stent. Then, while maintaining the  
5 position of the distal end of the stent, tube 40, to which the proximal end of the stent is  
6 secured, may be moved distally over tube 22. As a result, the distance between the two  
7 ends of the stent will be shortened and the diameter of the stent will approach, and may  
8 reach, its unconstrained, preformed diameter. In another embodiment, the proximal end  
9 of the stent may be positioned in its final location prior to shortening the stent. As such,  
10 tube 40 may be held steady and tube 22 may be moved proximally within tube 40 in order  
11 to shorten the stent. In another embodiment, the middle of the stent may be positioned in  
12 its final location prior to shortening, and tubes 22 and 40 may be moved toward each  
13 other by equivalent distances. The many manners in which the stent may be positioned  
14 and subsequently shortened during delivery thereof benefit the operator by providing him  
15 or her with the versatility necessary to deliver stents within a variety of anatomical  
16 structures.

17 The ability to compress the woven devices disclosed herein with the present  
18 delivery systems prior to releasing them is advantageous for several reasons. Not only  
19 does it assist the operator in achieving adequate contact between the woven device and  
20 the wall of the anatomical structure such that the woven device is anchored as securely as  
21 possible, it also allows the compressed device to occupy the least amount of space along  
22 the length of the anatomical structure as possible. When using the present occluders, for  
23 example, care should be taken to limit the space along the length of the structure where  
24 occlusion is taking place so as to avoid potential complications like the undesired  
25 occlusion of side branches, and the prevention of the formation of collateral vessels  
26 supplying the structures not affected by the treated lesion. Further, when using the  
27 present filters, for example, the space along the vessel available for filter placement may  
28 be limited by the presence of the thrombotic disease and/or other anatomical  
29 considerations, such as the proximity of renal veins in the IVC, the short, free segment of  
30 the SVC, etc.

1 Another advantage afforded by the present delivery system relating to the ability  
2 of an operator to manipulate either or both ends of the woven body being delivered prior  
3 to releasing those ends is the ability afforded the operator to position the present woven  
4 devices accurately in irregularly diseased anatomical structures. Anatomical structures  
5 are frequently irregularly stenosed; the distensibility or enlargeability of the diseased  
6 segment may be irregular due to the presence of tough scar tissue or a tumor, for  
7 example; and lengthy vessels are naturally tapered. Because both ends of one of the  
8 present woven devices may be simultaneously manipulated while using the middle of the  
9 woven device as a point of reference prior to release, the operator may be able to position  
10 the mid-portion of the device (such as a stent) proximate the mid-portion of the diseased  
11 segment of the vessel and maintain that relationship while simultaneously withdrawing  
12 tube 22 and advancing tube 40 so as to accurately position the stent along the diseased  
13 segment. Further, by increasing the ability of the operator to accurately position the  
14 woven device and, correspondingly, reducing the possibility that the woven device will  
15 need to be resheathed and reinserted, the present delivery systems allow the operator's job  
16 of delivery less potentially disruptive to the diseased segment of the patient.

17 Additionally, another advantage flowing from the fact that the present delivery  
18 systems allow for compression of woven devices lies in the resulting ability of the  
19 operator delivering a stent graft having a relatively non-stretchable graft material like  
20 PTFE to achieve a mesh tightness that, in turn, may serve to create better contact between  
21 both the woven stent and the graft material as well as between the stent graft and the wall  
22 of the anatomical structure.

23 One of the benefits of using the present stents with the present delivery systems is  
24 that the anatomical structure being treated can always be overstented. The diameter of an  
25 anatomical structure that is "overstented" is slightly smaller than the unconstrained  
26 diameter of the stent delivered therein. In contrast, overstenting is not necessarily  
27 achievable using delivery systems that do not possess the present delivery systems'  
28 capability to manipulate the distance between the ends of the device being delivered prior  
29 to stent release. Stents that are released using such delivery systems may remain



1 elongated within the anatomical structure into which they are delivered and, as a result,  
2 may not have a radial force sufficient to resist outer compression, which in turn could  
3 compromise the patency of the structure. Further, insufficient radial force could lead to  
4 stent migration. With the present delivery system, however, the present stents, for  
5 example, may be chosen such that their diameter is significantly greater than one hundred  
6 and ten percent of the anatomical structure being stented (110% being the norm for  
7 balloon-expandable stents, for example), such as one hundred and twenty percent, for  
8 example. Consequently, the present stents may be delivered so as to be slightly elongated  
9 within the anatomical structure in which they may be delivered (*i.e.*, the mesh tightness of  
10 the stent may be less than the tightest achievable), yet may retain enough expansile force  
11 to keep the structure patent, withstand outer compressive forces and be unlikely to  
12 migrate.

13       The overdistention or overstenting of an anatomical structure using one of the  
14 present stents that is substantially or completely compressed may be beneficial for several  
15 reasons. For example, the overstenting helps ensure that the stent will remain fixed in its  
16 original location and will not likely migrate. The inventors have discovered that when the  
17 present woven bodies are compressed prior to being released, they contact the anatomical  
18 structure more securely than if they are released without first being compressed. Further,  
19 as the overstenting may be achieved using a substantially or maximally compressed stent,  
20 the near-maximum or maximum radial force of the stent may also increase the stent's  
21 ability to withstand greater outer compressive forces without elongating and thereby  
22 compromising the patency of the structure being stented. Although *overstenting* is  
23 described above, those of skill in the art will understand with the benefit of the present  
24 disclosure that the same principle applies with equal force to the woven filters and  
25 occluders disclosed herein, and the single wire embodiments of each, and may be  
26 achieved in the same manner.

27       The Wallsten patent discloses a delivery system for the WALLSTENT that allows  
28 the distance between the ends thereof to be manipulated prior to the release of the  
29 WALLSTENT. However, this delivery system (depicted in FIGS. 5 and 6 of the Wallsten

1 patent) suffers from a number of shortcomings that are overcome by the present delivery  
2 systems. For example, the Wallsten delivery system involves a number of intricate parts  
3 (such as annular members, latches, rings, cables for displacing the rings, and a casing)  
4 that version 1 does not utilize and that would likely be time-consuming and expensive to  
5 manufacture and assemble. In contrast, the simple design of version 1 – *i.e.*, two tubes  
6 and multiple securing wires – has few parts, and those parts are easily obtainable.

7 Another advantage afforded by the present delivery systems is that the device  
8 being delivered is clearly visible during delivery. No parts, once any delivery sheath has  
9 been removed from around the present delivery systems, obstruct the view of the location  
10 of the ends of the device being manipulated. Additionally, the profile of the present  
11 delivery systems is no greater than that of the device being delivered over tube 40 (the  
12 larger of the delivery tubes). This is advantageous because the smaller the profile of the  
13 delivery system, the less likely the diseased segment of the structure will be unnecessarily  
14 disrupted or traumatized during the positioning and delivery of the woven device.

15 It is possible to overstent anatomical structures utilizing the present delivery  
16 systems and present stents through the longitudinal movement of tubes 40 and 22 in both  
17 version 1 and version 2, the latter of which is described below. As described above, these  
18 tubes may be moved relative to each other such that the stent being delivered is  
19 compressed maximally or nearly maximally prior to being released.

20 If the stent is not in the desired location after reaching its preformed diameter, it  
21 can advantageously be restretched and repositioned by moving tube 40, proximally and  
22 locking tube 40 to tube 22 if so desired. After locking has occurred, the stent may be  
23 repositioned and the process above described may be repeated as needed. This process  
24 may be complete when the stent is positioned in the desired location, and the stent fits in  
25 the vessel or non-vascular tubular structure in a way that the stent is nearly maximally  
26 expanded and/or the tissue of the vessel or non-vascular tubular structure is stretched  
27 slightly.

1           After performing this process, the distal end of the stent may then be released  
2 from its secured position. The distal end of the stent may be so released by pulling  
3 securing wire 30 (or wires) back into the lumen of tube 22. If the stent is still in the  
4 proper position, the proximal end of the stent may be released in the same manner so as to  
5 deliver the stent into the vessel or non-vascular structure, and the delivery system may be  
6 withdrawn back into a sheath and out of the body. If the stent is no longer positioned in  
7 the desired location after releasing the distal end of the stent, the stent may be pulled  
8 proximally back into a sheath by proximally moving tube 40 to which the proximal end of  
9 stent is still secured and/or distally moving the sheath. After doing so, the stent and  
10 delivery system may be removed from the body.

11           It is to be understood that the proximal end of the stent may be released from its  
12 secured position prior to releasing the distal end of the stent. Upon doing so, however,  
13 the ability to withdraw the stent back into a sheath (if a sheath is used) as described above  
14 is no longer present. Therefore, typically, the proximal end may be released first when  
15 the desired location of the stent will likely be maintained after such release.

16           In version 2, the stretched stent may be positioned in the desired location of the  
17 vessel or non-vascular tubular structure to be stented. Then, prior to unlocking the tubes,  
18 a sheath used to cover the stent, if used, may be proximally withdrawn so as to expose the  
19 stretched stent. Also prior to unlocking the tubes, outer sheath 70 covering inverse tabs  
20 60 may be moved proximally so that inverse tabs 60 are exposed (*see FIG. 5A*). In an  
21 exemplary embodiment, the outer sheath 70 may be withdrawn but not removed. The  
22 tubes may then be unlocked. It is to be understood that the tubes may be unlocked prior  
23 to withdrawing either a sheath used to cover the stretched stent, or outer sheath 70. Once  
24 this has occurred, either the distal end or proximal end of the stent may be released from  
25 its secured position as follows. In an exemplary embodiment, it may be preferable to  
26 release the distal end of the stent first because the secured proximal end may offer the  
27 possibility of removing a misplaced stent as above described. It is to be understood,  
28 however, that because of the completely controlled nature of the delivery system of the

1 present invention, the need to remove a misplaced stent may be very low, and, therefore,  
2 the proximal end of the stent may be released first without great risk.

3 When the distal end is to be released first, tube 40 may be moved distally over  
4 tube 22 (*see* FIGS. 5B and C) until the distal end of tube 40 reaches a pre-determined  
5 point located on tube 22, which in an exemplary embodiment, may be denoted through  
6 the use of a radiopaque marker. The point is located along tube 22 such that the proximal  
7 end of the stent will not be unhooked from inverse tabs 60 when the distal end of tube 40  
8 reaches it. When the point is reached by the distal end of tube 40, the tubes are locked  
9 together. Additionally, another marker may also be used on the proximal shaft of tube 22  
10 to denote the same point. If the stent is no longer in its ideal position at this point, outer  
11 sheath 70 may be moved distally and/or tube 40 may be moved proximally to cover  
12 inverse tabs 60, and the delivery system and the stent may be withdrawn into a sheath and  
13 removed from the body. If the proper position has been achieved, the distal end of the  
14 stent may then be released in the manner above described. Next, the proximal end of the  
15 stent may be released by unlocking the tubes, and moving tube 40 distally over tube 22  
16 until inverse tabs 60 release the openings or closed structures through which they were  
17 threaded. Tube 40 may then be further advanced distally until inverse tabs 60 are hidden  
18 or housed within sheath 52 as shown in FIG. 5D. At this point, the tubes may be locked  
19 together to maintain the position of the inverse tabs within sheath 52. After both ends of  
20 the stent have been released (*see* FIG. 5E), delivery system 50 may be withdrawn into a  
21 sheath and removed from the body.

22 In version 2, if the proximal end of the stent is to be released first, the sequence of  
23 events just described may occur (including the ability of the stent to be restretched and  
24 repositioned), except that the distal end of tube 40 may extend distally beyond the  
25 predetermined point such that inverse tabs 60 unhook the proximal end of the stent and  
26 then go on to being hidden or housed within sheath 52 as shown in d. of FIG. 5. After  
27 the proximal end has been released, the distal end of the stent may be released in the  
28 manner above described. At this point, the tubes may be locked together to maintain the

1 position of the inverse tabs within sheath 52. Delivery system 50 may then be withdrawn  
2 from the body as above described.

3 The delivery of the present stent grafts that utilize graft material that is stretchable  
4 as described above may be achieved with the same delivery systems and in the same  
5 manner as the delivery of the present "naked" stents. When a graft material that is  
6 formed from relatively non-stretchable material, such as PTFE, is utilized, however,  
7 although the same delivery systems may be utilized, the manner in which the stent graft  
8 may be delivered is slightly different from the manner in which the naked stents may be  
9 delivered in terms of the manner in which the stent graft may be repositioned, if  
10 necessary.

11 For example, if after releasing the distal end of the stent graft, whether the graft  
12 material is attached to the stent at the proximal or distal end thereof, the stent may be  
13 restretched over the delivery tubes and the stent's completely elongated position may be  
14 secured using the proximal lock mechanism. Then, the introducer sheath may be  
15 advanced over the proximal end of the stent graft, possibly as it is rotated, in order to  
16 recapture the graft material and the stent itself. Attaching the graft material to the stent at  
17 the proximal end thereof may make it easier to re-sheath the graft material using the  
18 process just described, and thus may facilitate repositioning, if necessary, because the  
19 graft material may take on a funnel shape prior to the release of the proximal end of the  
20 stent graft.

### 21 *Delivery of Stents in Side-By-Side Relationship*

22 The delivery of these stents may be accomplished relatively simultaneously, such  
23 that neither stent occupies more space within the aorta than does the other. Initially, the  
24 stents may be secured to either version of the delivery systems described above using the  
25 methods described above. As illustrated in FIG. 58A-D, in addition to securing the ends  
26 of the stent to tubes 22 and 40, the stent may also be secured to either tube (tube 22 as  
27 shown, for example) near the portion of the stent that will be positioned near the bilateral  
28 aorto-renal junction 830, which consists of aorta 832, left renal artery 834 and right renal

artery 836. FIGS. 58A-D illustrate only one stent being delivered, but it will be understood to those of skill in the art, with the benefit of this disclosure, that, as stated above, two stents may be released and delivered relatively simultaneously in the fashion described below. As shown, guidewire 203 may be utilized to enhance the maneuverability of the delivery system. (The fittings that may be used to secure tubes 22 and 40 to each, which are illustrated in FIGS. 25 and 26, are not illustrated in FIGS. 58A-D for the sake of simplicity.) This third secured portion may be achieved using the low-profile, tight securing loops described above. After stretching the stent on the delivery system and positioning the distal end of the stent in right renal artery 836 in the manner described above (FIG. 58A), the release and delivery of the stent may take place by first releasing the proximal end of the stent (FIG. 58B), then the distal end (FIG. 58C), and finally the portion of the stent near junction 830 (FIG. 58D). Tubes 22 and 40 and guidewire 203 may then be withdrawn from the patient. It will be understood to those of skill in the art, with the benefit of this disclosure, that the release of the various secured portions of the stents may take place in any order suited to the anatomical structure in question.

*Combined Treatment of Aneurysms Consisting of Stent Placement  
and Transcatheter Embolization*

In one embodiment of the present invention, the straight stent may be used for aneurysm treatment without being equipped with a graft material. In this embodiment, the "naked" stent may serve as a scaffold for developing an endothelial layer on the newly formed vessel lumen, while the aneurysmal sac may be excluded from circulation by transcatheter embolization.

Generally, the stent may be delivered into place, and an embolic agent 96 may be inserted into the surrounding aneurysmal sac as shown in FIG. 36.

As shown in FIG. 36, once the stent is in the appropriate position, an angiographic catheter 95 (5-French to 7-French) that is chemically compatible with the embolic agent (and not made from polyurethane when the embolic agent contains DMSO)

1 may be inserted and advanced into the lumen of the stent. In advancing the angiographic  
2 catheter into the lumen of the stent, one may use the same guidewire which may have  
3 been used in delivering the stent. However, one may advance the angiographic catheter  
4 without the use of a guidewire. An adequately sized microcatheter 97 (2-French to 4-  
5 French) that is also chemically compatible with the embolic agent may then be advanced  
6 through the angiographic catheter, on an appropriate size guidewire (0.014-inches to  
7 0.025-inches). The tip of the microcatheter may then be led through the weave of the  
8 stent into the aneurysmal sac. If the openings in the weave of the stent are approximately  
9 2.0 to 2.5 mm, angiographic catheter 95 may also be advanced into the aneurysmal sac.  
10 An embolic agent 96 may then be inserted into the aneurysmal sac through the  
11 microcatheter. Embolic agent 96 may be chosen so as to be: non-toxic, non-  
12 irritant/reactive to the tissues; easily handled; suitable for continuous injection;  
13 adequately radiopaque; capable of filling the space contiguously without leaving  
14 unoccupied spaces; and non-fragmented, thereby not getting back through the stent's  
15 weave into the newly formed lumen which could result in peripheral embolization.

16 Although, several fluid embolic materials (alcohol, poly-vinyl alcohol,  
17 cyanoacrylates, Ethibloc *etc.*) are available for transcatheter vessel occlusion, none of  
18 them is considered ideal or even suitable for this purpose. Recently, a nonadhesive,  
19 liquid embolic agent, ethylene vinyl alcohol copolymer (EVAL), has been used clinically  
20 for treatment of cerebral AVMs in Japan (Taki, AJNR 1990; Terada, J Neurosurg 1991).  
21 The co-polymer was used with metrizamide to make the mixture radiopaque and may  
22 serve as the embolic agent for the present invention.

23 Very recently, a new embolic agent (similar to EVAL), EMBOLYX E (ethylene  
24 vinyl alcohol copolymer) (MicroTherapeutics Inc., San Clemente, California) was  
25 developed which was designed for aneurysm treatment (Murayama, Neurosurgery 1998),  
26 and may be utilized as an embolic agent in one embodiment of the present invention. The  
27 embolic agent is composed of a random mixture of two subunits, ethylene (hydrophobic)  
28 and vinyl alcohol (hydrophilic). Micronized tantalum powder is added to it to obtain an  
29 appropriate radiopacity, and DMSO (di-methyl sulfoxide) is used as an organic solvent.

1 When the polymer contacts aqueous media, such as blood, the solvent should rapidly  
2 diffuse away from the mixture causing in situ precipitation and solidification of the  
3 polymer, with formation of a spongy embolus and without adhesion to the vascular wall.  
4 Any kind of material with characteristics similar to those of EMBOLYX E may be used  
5 as an embolic agent for the present invention.

6 The method just described may be utilized when the stent is covered as well. In  
7 such an embodiment, angiographic catheter 95, which may be 5-F in size, and  
8 microcatheter 97, which may be 3-F in size, may be advanced into the lumen of the covered  
9 stent as described above. A trocar, such as one having a 0.018-inch pencil-point or  
10 diamond-shaped tip and made of any suitable material such as stainless steel or nitinol,  
11 may then be inserted into the lumen of microcatheter 97. The sharp tip of the trocar may  
12 extend beyond the tip of microcatheter 97 by about 2 to 4 mm. The proximal ends of  
13 microcatheter 97 and the trocar may be locked together using a Luer lock mechanism. By  
14 doing so, a sheath-needle unit (well known in the art) may be created, which may then be  
15 used to puncture the graft material and the stent mesh. Thereafter, using fluoroscopy  
16 and/or CT in guiding the sheath-needle unit, the sheath-needle unit may be safely  
17 advanced into the aneurysmal sac. The trocar may then be removed, and microcatheter  
18 97 may be used for injecting the embolic agent as described earlier.

19 Both abdominal and thoracic abdominal aneurysms may be treated as above  
20 described. In some other locations (e.g., external iliac artery), pseudoaneurysm and/or  
21 tumor-induced corrosive hemorrhage may also be treated as above described.

22 The size of the delivery system that may be used to deliver a stent without a graft  
23 cover may be sufficiently small, such that insertion of the stent into the vessel may take  
24 place following a percutaneous insertion. The delivery system would also be well-suited  
25 to negotiating through tortuous vascular anatomy. The treatment described above may be  
26 performed using interventional radiology techniques, thereby eliminating the need for  
27 surgery. The embolization may occlude the lumbar arteries from which the excluded  
28 aneurysmal sac is frequently refilled. As a result of using the treatment described above,  
29 the endoleak from the patent lumbar arteries may be eliminated.



1       **2.       Filters**

2                               *Low-Profile Woven Cava Filters*

3               The wires of the cava filters of the present invention may be made of the same  
4 materials as the wires of the stents. The same number of wires may be used in forming  
5 the cava filters as are used to form the stents. However, in an exemplary embodiment,  
6 less wires are preferably used for the cava filters than for the stents. As with the stents, in  
7 an exemplary embodiment, as few as 5 wires may be used to form the cava filters for any  
8 given application except the single wire embodiment, which utilizes only one wire.

9               The cava filters may be created with a relatively loose weave allowing the blood  
10 to flow freely. In an exemplary embodiment, it is preferable that the distal end of the  
11 cava filters is not completely closed. *See FIGS. 6-8.* Instead, the bent ends of the wires  
12 (**FIG. 7** and **FIG. 8** show small closed loops, but bends may also be used) or the coupled  
13 ends of the wires (**FIG. 6**) are arranged to form a relatively round opening with a  
14 diameter of about 2 to 5 mm. The size of the wires that may be used for forming the cava  
15 filters other than the barbless stent filter (discussed below) ranges from between about  
16 0.009 inches and about 0.013 inches, but is most typically about 0.011 inches. The size  
17 of the wires that may be used for forming the barbless stent filter ranges from between  
18 about 0.008 inches and about 0.015 inches, but is most typically about 0.011 inches.

19              As with the stents of the present invention, the angle between the crossing wires  
20 of the cava filters is preferably obtuse. Similarly, at the proximal end (*e.g.*, **FIG. 6**) of the  
21 filter, either a loop or bend may be formed by bending the wires as above described.  
22 When such closed structures are made at the distal end of the filters, the angle formed  
23 may be acute as shown in **FIGS. 7, 8** and **9A**. At the distal (*e.g.*, **FIG. 6**) or proximal end  
24 (*e.g.*, **FIG. 7** and **FIG. 8**) of the cava filters, the wire ends may be coupled together to  
25 form closed structures as above described.

26              Advantageously, the portions of the wires forming the closed structures may be  
27 bent outwardly into multiple barbs to anchor the filter, when located at the proximal ends

1 of the cava filters (e.g., FIG. 7 and FIG. 8). As used herein, "barbs" are portions of the  
2 ends of the wires that may be used to form the cava filter. By carefully selecting the size,  
3 orientation and shape of the barbs, they may penetrate the vessel wall in order to better  
4 anchor the filter during use, but they may also be disengaged from the vessel wall as the  
5 filter is being retrieved but prior to the filter being withdrawn such that the possibility of  
6 causing any damage to the vessel wall is minimal. As illustrated in FIG. 59, barb 74 of  
7 closed structure 4 is penetrating vessel wall 73 at an angle 75 that is acute. Although  
8 angle 75 may be obtuse, the inventors have found that barb 74 generally anchors the  
9 filters more securely when angle 75 is acute rather than when it is obtuse. Beginning at  
10 side 77 of vessel wall 73 and extending to the end of barb 74, barb 74 may be about 1 to 2  
11 mm long. As shown, wire end 7 may be oriented at an angle that is roughly perpendicular  
12 to the angle of barb 74 such that barb 74 is prevented from more deeply penetrating vessel  
13 wall 73. Another example of suitably shaped barbs may also be found on the  
14 RECOVERY filter, which is commercially available from C.R. Bard, Inc.  
15 ([www.crbard.com](http://www.crbard.com); Murray Hill, NJ, 800 367-2273).

16 The cava filters of the present invention may be formed by plain weave using the  
17 methods described above for forming the stents. Of course, an appropriately shaped  
18 template may be chosen. Shapes for the cava filters include a cone (FIG. 6 and FIG. 7),  
19 a dome (FIG. 8), an hourglass shape (FIG. 9), and the shape of the barbless stent filter  
20 (FIG. 51). The cava filters may also be heated as the stents are, and may be allowed to  
21 cool as the stents are. Additionally, in an exemplary embodiment, as with the tapered  
22 stent, the filters may be woven on a cylindrical template, heated and allowed to cool, then  
23 the body formed may be remodeled and then reheated on another template. In an  
24 exemplary embodiment of the hourglass filter, for example, the body formed by weaving  
25 may be heated and cooled, and then may be remodeled into the shape of an hourglass by  
26 narrowing the central portion using a material suitable for reheating such as copper/brass  
27 wire; then the hourglass shaped body may be reheated.

28 In an exemplary embodiment of the cava filters of the present invention, it may be  
29 preferable to flare and compress the woven structure near the proximal end of a conical or

1 dome shape filter or near both the proximal and distal ends of an hourglass filter, forming  
2 a cylindrical portion with a relatively tight weave (*see* portions 140 in **FIG. 6**, **FIG. 7** and  
3 **FIG. 9**) prior to heating. The diameter over this portion may be virtually constant. In an  
4 exemplary embodiment, this portion may be formed using the above-described method of  
5 heating and cooling a filter that may not possess the desired portion, reconstraining or  
6 remodeling the filter to achieve the desired shape of the portion, securing the given  
7 portion of the filter in the desired shape and heating and cooling the constrained filter  
8 again.

9 In an exemplary embodiment, this constant-diameter portion and/or the flared  
10 ends of the cava filters may be advantageously used for anchoring. By achieving strong  
11 contact between the filter and the vessel wall, the filter's intraluminal position can be  
12 further secured. The expansile force of the cava filter (which depends partly on the  
13 number and size of the wires which are used for making the structure) may be chosen so  
14 as to ensure such strong contact. The use of the flared portions as well as the suitable  
15 barbs may virtually eliminate the possibility of migration.

16 The cava filters of the present invention will be further described in more detail  
17 below by the way of specific examples.

18 **a. Conical Filter - FIGS. 6 and 7**

19 With reference to the illustrative embodiments shown in **FIGS. 6** and **7**, there are  
20 shown conical filters for insertion and delivery into vascular anatomical structures. The  
21 conical filters include a plurality of wires which may be arranged in a plain weave as  
22 described above so as to define an elastically deformable body 150. As shown in **FIGS. 6**  
23 and **7**, body 150 has a wide and/or flared proximal end 142 and a distal end 144. The  
24 diameter of body 150 is larger at proximal end 142 than at distal end 144. The diameter  
25 of body 150 decreases from proximal end 142 to distal end 144. Distal end 144 may be  
26 formed in such a way that almost no opening is left through which fluid might flow. As  
27 discussed above, however, in an exemplary embodiment, it is preferable to leave a  
28 relatively round opening with a diameter of about 2 to 5 mm.

1           **b.     Dome Filter - FIG. 8**

2           With reference to the illustrative embodiment shown in **FIG. 8**, there is shown a  
3 dome filter for insertion and delivery into a vascular anatomical structure. The dome  
4 filter includes a plurality of wires which may be arranged in a plain weave as described  
5 above so as to define an elastically deformable body 152. As shown in **FIG. 8**, body 152  
6 like body 150, may have a wide and/or flared proximal end 142 and a distal end 144. The  
7 diameter of body 150 is larger at proximal end 142 than at distal end 144. The diameter  
8 of body 150 decreases from proximal end 142 to distal end 144. The degree of the  
9 decrease in the diameter from the proximal to the distal end is not as steep as in the  
10 conical version, however. As a result, body 152 more resembles a hemisphere than a  
11 cone. Because of its hemispherical shape, the dome filter may occupy less longitudinal  
12 space within the cava than other filters.

13           **c.     Hourglass Filter - FIG. 9**

14           With reference to the illustrative embodiment shown in **FIG. 9**, there is shown an  
15 hourglass filter for insertion and delivery into a vascular anatomical structure. The  
16 hourglass filter includes a plurality of wires which may be arranged in a plain weave as  
17 described above so as to define an elastically deformable body 154. As shown in **FIG. 9**,  
18 body 154 has two conical or dome portions 146 bridged by a narrow portion 148. The  
19 diameter of distal and proximal ends 144 and 142 is larger than the diameter of portion  
20 148. In an exemplary embodiment, distal end 144 is preferably not equipped with barbs.  
21 The closed structures of proximal end 142 may be bent outwardly to form barbs. The  
22 lumen size of narrow portion 148 may be selected so as not to close the lumen of the filter  
23 completely. The hourglass filter shown in **FIG. 9** has multiple filtrating levels; in an  
24 exemplary embodiment there may be almost no difference in the filtrating capacity  
25 between the filtrating capacity of the center of the filter and the filtrating capacity of the  
26 periphery of the filter because the blood may be filtered by the peripheral weave of both  
27 the proximal and distal portions 146. **FIG. 10** shows an hourglass filter placed in the  
28 IVC.

d. **Barbless Stent Filter – FIG. 51**

With reference to the illustrative embodiment shown in **FIG. 51**, there is shown a barbless stent filter for insertion and delivery into a vascular anatomical structure. The barbless stent filter includes a plurality of wires which may be arranged in a plain weave as described above so as to define body **400**, which, like all the other bodies in this disclosure, is suitable for implantation into an anatomical structure. As shown in **FIG. 51**, body **400** may consist of base **402**, mid-portion **404**, and dome **406**.

Base **402** may be made as a straight stent (as described above) with a given diameter. As a result, base **402** may serve to anchor the filter within a vessel and may not participate in blood filtration. In another embodiment of this filter, base **402** may also be made with a changing diameter. For example, its lumen may be slightly tapered from base **402** to mid-portion **404**. The mesh tightness of base **402** may approach the maximum-achievable tightness (*i.e.*, 180°). Accordingly, the radial force of the anchoring portion (base **402**) will increase as the mesh tightness increases.

Additionally, by carefully selecting the diameter of base **402**, body **400** may be configured to retain its position within a vessel without the use of barbs. As a result, the task of carefully selecting the size, orientation, and shape of the barbs that could otherwise be used such that those barbs may be elevated from the caval wall so as to greatly reduce the possibility of damaging the vessel wall during resheathing (as a result of repositioning or removing the filter) may be eliminated. In an exemplary embodiment of the barbless stent filter, the diameter of base **402** may be 26-30 mm, which represents operable diameters in ninety-five percent of the population, which has an inferior vena cava of less than 28 mm in diameter. In an exemplary embodiment of the barbless stent filter, the length of base **402** may not exceed 10-15 mm.

As shown in **FIG. 51**, mid-portion **404** of the barbless stent filter includes struts **408**, which are formed of twisted wires **5**. Struts **408** are arranged so as to be oriented in substantially parallel relationship with the axis of the portion or segment of the vessel in which they are delivered or released. Struts **408** may serve to further stabilize the

1     barbless stent filter within the vessel or non-vascular structure into which the filter is  
2     delivered. For example, in the embodiment of the barbless stent filter shown in **FIG. 52**,  
3     struts **408** may be slightly bent or bowed outward so as to increase the frictional forces  
4     between the delivered filter and the vessel wall. As a result, the self-anchoring capability  
5     of the filter may be increased. In an exemplary embodiment of the barbless stent filter,  
6     the length of mid-portion **404** may be about 5-10 mm.

7             Turning to the third portion of the barbless stent filter, as shown in **FIG. 51**, the  
8     mesh tightness of dome **406** may be loose. In one embodiment of this filter, the top  
9     portion of the dome may be equipped with hook **410** to facilitate the removal of the filter.  
10    In such an embodiment, hook **410** may be small and made of metal or any other suitable  
11    material, and may be firmly and permanently attached to wires **5**. Similarly, although not  
12    illustrated, with the benefit of the present disclosure one of ordinary skill in the art will  
13    understand that hook **410** may also be provided on the proximal ends of the other cava  
14    filters disclosed herein. Additionally, the hooks on these filters may be used during the  
15    possible repositioning or retrieval of such filters in the same way as may be used on the  
16    barbless stent filter, described below in greater detail.

17            In another embodiment, the barbless filter may be provided with two filtration  
18    levels. As shown in **FIG. 53**, such a filter is composed of two domes **406** (arranged  
19    inversely), a mid-portion **404** having a tight stent mesh similar to the mesh of base **402** in  
20    the embodiments in **FIGS. 51** and **52**, and two, intermediate segments **412** having short,  
21    struts **408** between domes **406** and mid-portion **404**. In one version of this embodiment,  
22    both the top and bottom portions of the domes may be equipped with hook **410** to  
23    facilitate the removal of the filter. Alternatively, either the top or bottom may be  
24    equipped with hook **410**.

25            The end of the barbless stent filters located proximate hook **410** depicted in **FIGS.**  
26    **51-53** may be positioned so as to achieve a variety of configurations. For example, the  
27    end may be stretched such that the shape of domes **406** is closer to a triangle than the  
28    shape depicted in **FIGS. 51-53**, or the end may be compressed.

1           The shape of the barbless stent filters may be formed using the methods described  
2 above for forming the stents and other cava filters. For example, the barbless stent filter  
3 may be woven on an appropriately shaped template. Then the filter and template may be  
4 heated and cooled as above described. Alternatively, the barbless stent filter may be  
5 woven on a cylindrical template and heated and allowed to cool. Alternatively, prior to  
6 heating and cooling, certain portions such as the mid-portion and dome may be  
7 reconstrained or remodeled, and the remodeled portion of the filter may then be secured  
8 and heated and cooled again.

9           **e. Biodegradable filters**

10           As indicated above, all of the filters of the present invention (including the BI  
11 filter discussed below) may be formed with filaments made of biodegradable material so  
12 as to form self-expanding, self-anchoring, bioabsorbable, biodegradable filters that may,  
13 in addition to functioning as filters, function as drug or nutrient delivery systems as a  
14 result of the material used. In one embodiment, the biodegradable filters of the present  
15 invention may be provided with reinforcement wires as above described.

16           The factors that may be considered in choosing the materials from which to form  
17 the biodegradable stents, the materials themselves, the methods of forming the  
18 biodegradable stents and reinforcing the stents with wires, apply to the filters as well. In  
19 addition, one may also consider the following: the flow conditions of the vessel into the  
20 biodegradable filters are placed (*e.g.*, high flow conditions within the vena cava), to better  
21 ensure that the material and weave of the filter are chosen such that the filter may anchor  
22 properly within the vessel; the rate of degradation of the chosen material as well as the  
23 time at which the degradation will begin so that if the filter is used as a temporary filter  
24 (as described below), the entrapped thrombi may be attended to before the filter degrades  
25 to an extent that the entrapped thrombi could be released back into the bloodstream.

26           Any of the cava filter embodiments disclosed herein may be made from both  
27 wires 5, (wires 5 may be made from any of the materials described above, such as nitinol)  
28 and appropriate biodegradable filaments 540. Although the barbless stent filter is

1 described below in this regard, it is by way of example only, and with the benefit of the  
2 present disclosure, one having skill in the art will understand that wires 5 and  
3 biodegradable filaments 540 may be connected to each other as hereinafter described for  
4 the other embodiments of the cava filters disclosed herein.

5 Base 402 may be formed from wires 5, while dome 406 may be formed from  
6 filaments 504, which may be formed from an appropriate biodegradable material, such as  
7 one described above in greater detail. In this embodiment, the transition between the two  
8 materials may be created in mid-portion 404. The connection between each nitinol wire  
9 and the corresponding filament may be made by using any suitable means such as glue,  
10 heat, by wrapping the filament around the wire, or any combination of thereof. After  
11 biodegradation of dome 406 has taken place, base 402 may, like a self-expanding stent,  
12 be left behind in the body.

13 **f. Single-wire embodiment filter**

14 As with the occluders, the single wire embodiment may also be utilized as a  
15 structure for filtering thrombi within a vessel. The single wire embodiment filters may be  
16 formed in the same manner as the single wire embodiment occluders are formed.  
17 Moreover, the single wire embodiment filters are simply the single wire embodiment  
18 occluders without any thrombogenic agents attached to the body of the single wire  
19 embodiment filters. In this regard, FIG. 60 illustrates body 700 of a single wire  
20 embodiment filter. The body has first segment 704 and second segment 706 separated by  
21 a bend in the wire that is in the form of closed loop 6. The body is provided with  
22 multiple collars 702, which hide multiple loop-defining locations where the segments are  
23 positioned adjacent to each other. (Adjacent has the same meaning with respect to the  
24 single wire embodiment filters as it has with respect to the single wire embodiment  
25 occluders.) The segments 704 and 706 extend between the loop-defining locations so as  
26 to form multiple loops 710, which are designated in FIG. 60 by the segments that outline  
27 them. Another embodiment of the present single wire filters is illustrated in FIG. 15. As  
28 illustrated in both FIGS. 60 and 15, loops 710 of bodies 700 possess compressed shapes.



### *Delivery System of the Cava Filters*

Version 1 shown in **FIG. 3** may be used as the delivery system for the cava filters (including each of the versions described above) according to the present invention.

### *Delivery of the Cava Filters*

Prior to insertion and delivery, a cava filter in the form of a body **150**, **152**, **154**, **400** (or biodegradable versions thereof), or body **700** may be manually secured to tubes **22** and **40** of version 1 as above described. The cava filter may then be stretched as described above so as to reduce the diameter of its largest portion by an amount appropriate such that the filter may be inserted into a vessel (preferably with the use of an access sheath), and may pass through the lumen of the vessel as the filter is being positioned prior to being delivered into the vessel. **FIG. 28** shows a filter secured to a delivery system in a completely stretched state.

In one embodiment of the method for delivering the cava filters of the present invention, a hollow covering such as a guiding sheath may be placed over the filter secured to the delivery system to prevent contact between the filter and the vessel wall as the filter is inserted and positioned for delivery. In another embodiment, a short, introducer sheath with a check-flo adapter may be used at the access site to prevent contact between the filter and the vessel into which the filter may be inserted during insertion of the filter; in such an embodiment the introducer sheath may or may not be used to cover the filter beyond the access site of the vessel.

The cava filters of the present invention may be stretched completely on the delivery system, reducing their diameters as much as possible, as shown in **FIG. 28**, for example. In one embodiment, after being secured to the delivery system and stretched to some extent, a filter may be delivered into the inferior vena cava ("IVC"). In such an embodiment, the filter may be inserted into either the right or the left femoral vein, allowing for a femoral approach. In such an embodiment, the filter may be inserted into the internal jugular vein, allowing for a jugular approach. In such an embodiment, a filter

1 and delivery system with a relatively small profile, such as 7-F, for example, may be  
2 inserted into a peripheral vein (pl. antecubital vein), allowing for a peripheral approach, if  
3 the system is sufficiently flexible. As discussed above with regard to the delivery of the  
4 stents, the construction of the delivery system enables one to use a guidewire in the lumen  
5 of tube 22 for delivery of the filter, in an exemplary embodiment of the present invention.  
6 It is to be understood however, that a guidewire may not be utilized at times.

7 Each of the cava filters may be delivered into place in the manner described above  
8 with regard to the delivery of the stents using version 1 (*see, Delivery of the Stents*). All  
9 the advantages described above with regard to repositionability, *etc.*, including the  
10 advantage of being able to compress the filter being delivered and achieve as tight a mesh  
11 in the cylindrical portions thereof (such as base 402 of the barbless stent filter) as  
12 possible, apply equally to the delivery of the cava filters. Further, in instances in which  
13 one of the present cava filters is delivered in the IVC, for example, the elasticity of the  
14 IVC wall allows the operator to achieve an even tighter mesh than the mesh originally  
15 created after the annealing process. That is, a filter configured with an angle  $\alpha$  of  $155^\circ$   
16 may be compressed during delivery until angle  $\alpha$  is  $170^\circ$ , and, if the filter is properly  
17 oversized, the elasticity of the IVC wall may maintain angle  $\alpha$  at very close or equal to  
18  $170^\circ$ . The ability of the present delivery system to achieve this scenario is especially  
19 advantageous when the filter is created without barbs so as to maintain its position within  
20 the vessel into which it may be delivered by virtue of the radial force between the filter  
21 and the vessel wall.

22 The weave of the present filters (including those discussed below) is especially  
23 suitable to advantageously allow mechanical thrombus-suction to remove the entrapped  
24 clots without the risk of dislodging the thrombi and allowing them to travel to the  
25 systemic and pulmonary circulation. In so doing, an adequately sized catheter with a  
26 large lumen may be inserted into the filter's lumen and used to suck the thrombi out.  
27 This method may be used in combination with thrombolysis.

1           a.       **Non-permanent cava filter applications**

2           All of the woven cava filters, particularly the conical, dome, and barbless stent  
3 filters, may be used in temporary applications. A basic need exists to remove entrapped  
4 thrombi safely and successfully before removal of a temporary filter. The emboli  
5 entrapped by any kind of temporary filter can be dealt with in a variety of ways, such as  
6 thrombolysis, placement of a permanent filter, or allowing small thrombi to embolize to  
7 the lungs. The woven structure of the cava filters of the present invention seems  
8 favorable to prevent escape of the entrapped clots during thrombolysis. As a result, there  
9 is probably no need to place another filter above the woven temporary filter. This would  
10 otherwise be impossible if the temporary filter is delivered from a jugular approach. The  
11 temporary applications of the cava filters include both temporary and retrievable filter  
12 designs.

13           Temporary filters may be attached to a catheter or sheath, a tube or a guidewire  
14 that may project from the insertion site (*e.g.*, using a hub with a cap which is sutured to  
15 the skin for fixation), so as to allow for easy removal of the filter. Retrievable filters are  
16 permanent filters that have a potential to be removed.

17           Both the temporary and the retrievable filters may be delivered *via* a jugular  
18 approach. It is to be understood, however, that these filters may also be delivered *via* a  
19 femoral or antecubital approach.

20           In one embodiment, a temporary filter may be created by manually securing a cava  
21 filter to two tubes in the manner described above. The outer tube to which the proximal  
22 end of the filter may be secured may comprise a catheter or sheath, or it may comprise a  
23 tube such as tube 40 described above. Being a low profile design, the temporary filter  
24 typically does not require an outer tube larger than 7 French.

25           After properly positioning the temporary filter, the distal end of the temporary  
26 filter may be released using the above described method. If the temporary filter is no  
27 longer in the proper position, the filter may be withdrawn as shown in **FIGS. 27A and B.**

1       FIGS. 27A and B illustrate tube 71 (which may, for example, be any suitably-sized  
2       catheter or sheath) being advanced over a filter such that barbs 74 of the filter that  
3       penetrate vessel wall 73 are disengaged from vessel wall 73 as tube 71 is advanced and  
4       the filter is held stationary. A monofilament (not shown) may be threaded through one or  
5       more of the bends or closed loops defining the proximal end of the filter. Both ends of  
6       the monofilament may be positioned in an easily accessible location (such as exterior of  
7       the patient). The operator can then advance tube 71 over the ends of the monofilament  
8       (as described below with respect to monofilament loop 172 depicted in FIG. 12) while  
9       holding the monofilament steady to disengage barbs 74 from vessel wall 73 prior to the  
10      withdrawal of the filter.

11           After releasing the distal end of the filter, the holes in the superelastic tubing  
12      through which the securing wire or wires were threaded may be used for injection of  
13      some urokinase or tissue plasminogen activator (TPA) to lyse entrapped thrombi within  
14      the mesh. FIG. 26 depicts the situation in which the distal end of the filter has been  
15      released. As shown in FIG. 26, openings 27 may be provided in tube 22, in addition to  
16      proximal and distal holes 24 and 26, through which urokinase or TPA may as just  
17      described. FIG. 26 also depicts introducer sheath or catheter 99, which may be utilized  
18      in conjunction with the present delivery system to facilitate the insertion of the delivery  
19      system, including tubes 22 and 40, into the patient. (Note that push button lock/release  
20      mechanism 200 shown in FIG. 25 as connecting tube 40 and 22 is not depicted in FIG.  
21      26.) Introducer catheter 99 may be attached to end fitting 204, as shown in FIG. 26, with  
22      a Luer connection. FIG. 26 also illustrates that multiple securing wires 46 may be  
23      utilized for securing the proximal end of the filter to tube 40. In this regard, although not  
24      shown, it will be understood to those of skill in the art, with the benefit of this disclosure,  
25      that securing wires 46 may be controlled by creating openings in tube 40 near the  
26      proximal end of tube 40 and threading the proximal ends of securing wires 46 through  
27      those holes. In this way, the proximal end of the filter or other device may be released by  
28      pulling the proximal ends of securing wires 46. Tightening screw 205 may be provided  
29      on the end of the side arm of end fitting 204, as shown in FIG. 26, for fixing the relative  
30      positions of securing wires 30 (not shown). Additionally, although not shown, it will be

1 understood to those of skill in the art, with the benefit of this disclosure, that a tightening  
2 screw may be provided on the end of end fitting 204 for fixing or securing the relative  
3 position of any guidewires that are utilized as well.

4 In this embodiment of the invention, there may be no need to apply barbs/tabs at  
5 the distal end of the temporary filter. For example, the barbless stent filter, by nature, will  
6 not be equipped with barbs. However, such barbs or tabs may be supplied as shown in  
7 FIG. 27A to the other filters. The proximal end of the outer tube may be secured to the  
8 skin using surgical sutures. When the filter is to be removed, the temporary filter may be  
9 withdrawn into a catheter/sheath (such as tube 71) and the device may be withdrawn from  
10 the body.

11 An additional manner in utilizing the barbless stent filter as a temporary filter  
12 exists that does not involve leaving an outer tube in the body. In one embodiment, hook  
13 410 may be used as a tool for removing a temporary filter. At the appropriate time, a  
14 foreign body snare, such as the Amplatz Goose Neck snare (Microvena Corp., White Bear  
15 Lake, MN) may be used to grasp hook 410 and retract the filter into an appropriately  
16 sized thin-walled sheath for removal from the body. The snared end of the filter may be  
17 held stationary and an appropriately-sized sheath (approximately 2-French sizes larger  
18 than the delivery system) may be advanced over the shaft of the foreign body snare to  
19 capture the filter.

20 For the retrievable filter, the distal end may be equipped with barbs/tabs. At the  
21 proximal end of the retrievable filter, a monofilament loop is threaded through the small  
22 closed loops (or bends) created from the bent wires such that the small closed loops  
23 become interconnected by the monofilament loop (*see, e.g., FIG. 12*); thus, pulling on the  
24 monofilament loop will result in drawing the small closed loops together thus reducing  
25 the diameter of the stent at the proximal end. The retrievable filter may be secured to the  
26 same delivery system used for delivery of the temporary filter in the same way.

27 Delivery may also be carried out in the same way. In an exemplary embodiment,  
28 the filter may be delivered from a right jugular approach. It is to be understood that if the

1 delivery system is small enough, an antecubital approach may be acceptable, especially  
2 for a short time filtration. It is to be understood that delivery from a femoral approach  
3 may require the filter to be positioned inversely. After delivery of the retrievable filter  
4 from a jugular approach, for example, the delivery system may be removed and only the  
5 monofilament loop may be left within the vasculature. The very proximal end of the loop  
6 may be attached to the skin as above described. In this form, the retrievable filter may be  
7 used as a temporary filter. Both the flared base with the tighter mesh and the barbs/tabs  
8 may serve to anchor the retrievable filter within the cava. In the case of the barbless stent  
9 filter, base 402 may serve the function of the flared base of the other filters, which may or  
10 may not be provided with barbs or tabs. If it is necessary to convert the temporary filter  
11 into a permanent one, the monofilament loop may be severed and removed from the small  
12 closed loops of the filter as well as from the body.

13 If a decision is made to remove a retrievable filter, a short metal straightener may  
14 be advanced over the proximal end of the monofilament loop. A short introducer sheath  
15 may then be inserted in the access vein over the straightener. Through the introducer, an  
16 adequate size sheath may be advanced to the distal end of the filter. Stretching the  
17 monofilament loop, the sheath may be advanced over the filter. As a result, the  
18 barbs/tabs, if utilized, will be retracted from the caval wall, and the filter's removal can  
19 be achieved without causing injury to the vessel wall.

20 The time period for leaving a temporary filter in a patient will vary from case to  
21 case, but, generally, temporary filters may be left in place for no more than about two to  
22 three weeks. Leaving them in place for a longer period of time may result in the  
23 formation of a neointimal layer on the temporary filter, which would impede its removal.  
24 To increase the period of time during which these filters may be left in the body without  
25 being embedded into the neointimal layer, the filters may be coated with some  
26 biologically active materials (*e.g.*, cytostatics, fibroblast growth factor [FGF-1] with  
27 heparin, Taxol, *etc.*) or the metal of the filter may be rendered  $\beta$ -particle-emitting  
28 producing a low-rate radiation at the site of the filter placement (Fischell, 1996).

1           The main advantage of the retrievable filter is that if the conversion from  
2 temporary to permanent filtration is necessary, there is no need to remove the temporary  
3 filter and deploy a permanent one. Both versions are suitable for intraluminal  
4 thrombolysis both from a jugular or a femoral approach or possibly an antecubital  
5 approach.

6           The retrievable filter provides additional advantages in that they are easily  
7 retrievable, they possess equal filtering capacity in the center and at the periphery of the  
8 cava, they provide safe thrombolysis, they are self-centering and self-anchoring, and  
9 unless hook 410 is utilized in conjunction with the barbless stent filter, it is unnecessary  
10 to use a foreign-body retrieval device which might involve lengthy manipulations.  
11 However, it is to be understood that, in some embodiments, small tabs may be coupled to  
12 the ends of the filters of the present invention for facilitating the removal of the filter with  
13 a foreign body retrieval device.

14           The cava filters of the present invention provide the advantage of improved  
15 filtration. The extended coverage of the filtering level comes with an improved thrombus  
16 capturing capacity of the cava filters. The presence of a thrombus in a traditional conical  
17 filter decreases the capture rate for a second embolus (Jaeger, 1998). The succeeding  
18 thrombus will not be able to get into the apex of the cone and has a higher chance of  
19 passing through the filter (Kraimps, 1992). The flow velocity, and therefore, the  
20 hydrodynamic force are increased at the stenotic site of the filter. Because conical filters  
21 predominantly capture thrombi in the apex of the cone, the site of increased velocity is  
22 located at the periphery of the filter. As long as the diameter of the thrombi is smaller  
23 than or equal to that of the stenotic opening, the locally increased velocity and  
24 hydrodynamic force will push the thrombi through the filter periphery.

25           Using the cava filters of the present invention, the thrombi will be primarily  
26 captured by the distal end of the conical and dome filters and by the dome of the barbless  
27 stent filter; in the case of the hourglass filter, the first filtration level is the narrow portion  
28 of the proximal end of the filter. Any subsequent emboli will be diverted to the periphery

1 of the cava where the filter has approximately the same filtration capacity as in the center  
2 of the filter.

3 The filtration capacity of a filter can be estimated by looking at it from the top or  
4 below. The wires/mesh arrangement in the projected cross-section of the filtered segment  
5 of the IVC gives a good estimate about the "coverage" of the IVC by the filter. For  
6 example, **FIG. 29** depicts a projected cross section of one of the present hourglass filters  
7 taken across the middle portion of the filter. In the case of the hourglass filter, the blood  
8 is primarily filtered by the proximal half of the filter, similar to the case using the dome  
9 or conical filter. The blood which is going proximally alongside the caval wall will be  
10 filtered the peripheral mesh of both the proximal and the distal "dome". As a result, as in  
11 the case of the barbless stent filter, there is virtually no difference in filtration capacity of  
12 the filter in the center and at the periphery of the vessel. Additionally, with respect to  
13 each of the filters, the immediate opening and symmetric arrangement of the bases of the  
14 filters serves to self-center them and prevent them from being tilted. Some filter designs  
15 (especially the Greenfield-filter) are sensitive to intraluminal tilting, which negatively  
16 affects their filtration capability.

17 The flexibility of the mesh of the cava filters, as is the case with all the woven  
18 intravascular devices of the present invention, makes it possible to advance the delivery  
19 system through tortuous vessels. This feature together with the small size of the delivery  
20 system enables one to deliver these filters *via* every possible access site of the body.  
21 Further, as with all the intravascular devices of the present invention, the plain weave of  
22 the cava filters allows for the production of one coherent element, which does not possess  
23 any kind of joints.

24 The cava filters according to the present invention may possess (depending on the  
25 material used to form the wires thereof) a non-ferromagnetic character making them, as  
26 well as stents formed therefrom, MRI compatible.

27 The cava filters of the present invention are also suitable for intravascular  
28 thrombolysis. After placement of any kind of filtering device, the development of caval



1 thrombosis/occlusion frequently occurs (Crochet, 1993). In acute cases, a possible  
2 therapeutic option is to recanalize the IVC by pharmaco-mechanical thrombolysis. Doing  
3 so in the presence of the currently available filters poses a high risk of developing  
4 pulmonary emboli, because large fragments of the IVC thrombus can break off and be  
5 carried away in an uncontrolled way after urokinase/TPA treatment. One of the  
6 acceptable options in that situation is to place another filter above the thrombosed filter to  
7 avoid pulmonary embolism due to thrombolysis. Unlike other designs, the cava filters  
8 according to the present invention may offer the possibility of a safe and successful  
9 thrombolysis without the need for the placement of two filters.

### 10 *Bi-Iliac Tube Filter*

11 The wires of the BI filter according to the present invention may be made of the  
12 same materials as the wires of the stents. The same number of wires may be used in  
13 forming the BI filter as are used to form the stents. However, in an exemplary  
14 embodiment, less wires are preferably used for the BI filter than for the stents. It is to be  
15 understood that although only 4 wires appear in FIGS. 11-13, 2 more wires are not  
16 shown. The BI filter may be created with a relatively loose mesh allowing the blood to  
17 flow freely. The size of the wires that may be used for forming the BI filter ranges from  
18 between about 0.008 inches and about 0.011 inches, but is most typically about 0.009  
19 inches.

20 The BI filter according to the present invention may be formed using the above  
21 described methods for forming the stents. Of course, an appropriately shaped template  
22 may be chosen. In weaving body 160 of the BI filter, as shown in FIGS. 11-13, the angle  
23  $\alpha$  between the crossing wires is preferably obtuse. It is to be understood that angle  $\alpha$  may  
24 also be less than or equal to 90°. End 164 may have a plurality of closed structures which  
25 may be small closed loops 166 (FIGS. 12 and 13) or bends 168 (FIG. 11), like the above  
26 stents and filters. The angles of those closed structures may be similar to the angles for  
27 the closed structures of the stents as above described. The wire ends at 162 of body 160  
28 may be coupled together in the manner above described.

1           Body **160** of the BI filter may also be heated as the stents are, and may be allowed  
2           to cool as the stents are.

3           In one embodiment, the mid-portion of the BI filter may be constructed with a  
4           larger diameter than that of the ends which are used for fixation. This may be achieved in  
5           a variety of ways using the remodeling methods above described. For example, one may  
6           weave a straight stent with a caliber useful for filtration (larger lumen). Then, smaller  
7           caliber ends may be formed by remodeling the filter on a smaller caliber template. In  
8           such a case, the weave of the filtering level will be looser than those of the legs. In  
9           another embodiment, the weave of the filtering level may be tighter than those of the legs  
10          by weaving the BI filter is on a template sized for the legs, and then remodeling the filter  
11          by ballooning the mid-portion of the filter outward. Many variations in shape are thus  
12          possible.

13          The BI filter of the present invention may be stretched completely on the delivery  
14          system, reducing its diameter as much as possible. It may be delivered in that stretched  
15          state into the inferior vena cava ("IVC"). It is to be understood that it may also be  
16          delivered into the IVC in a state that is not completely stretched. The filter may be  
17          inserted from either femoral vein and placed into both iliac veins forming an inverse  
18          U-shape bridging over the confluence of these veins. Unlike traditional IVC filters, the  
19          filtration according to the present invention will substantially take place through the  
20          cephalad surface **163** of the weave at about the mid-portion of body **160** located at the  
21          junction of the iliac veins, as shown in **FIG. 11**.

22          The BI filter is suitable for temporary filtration. In this embodiment of the present  
23          invention shown in **FIG. 12**, the coupled wire ends form the distal end of the filter, while  
24          the multiple small closed loops **166** located proximally are connected by a monofilament  
25          loop **172** as described above and shown in **FIGS. 12** and **13**. **FIGS. 12** and **13** illustrate  
26          Bi-filter **160** delivered within left iliac vein **157** and right iliac vein **158**, beneath the  
27          inferior vena cava **159**. Using a contralateral approach, the filter may be inserted from  
28          either femoral vein and its front end may be positioned into the contralateral iliac vein.  
29          After delivery of the filter, the monofilament loop may be led outside the body and

1     secured to the skin. When there is no further need for the filter, it may be withdrawn by  
2     pulling it back by the monofilament loop through an advanced sheath.

3             In another possible embodiment of this invention shown in **FIG. 13**, a flexible,  
4     superelastic wire or microtubing **174** made from nitinol (or similar superelastic/shape  
5     memory material described above) is led through the lumen of the BI filter. The distal  
6     end of the nitinol wire/microtubing is attached or coupled to one twisted wire-end **170** of  
7     the filter by any suitable means, including soldering, point welding, wrapping of fibers,  
8     and the like. The proximal end of the wire/microtubing may be attached to the skin  
9     (along with the monofilament loop). When the BI filter is being withdrawn, the  
10    wire/microtubing may be held steadily, while the monofilament loop is pulled. As a  
11    result, the BI filter will be partially stretched facilitating the filter's removal. The BI filter  
12    may also be removed in the fashion described above for removing the temporary filter.

13            As discussed above, given the design of the BI-filter, one may catheterize the  
14    lumen of the filter and, using an adequate size catheter, thrombus-suction may be easily  
15    performed before filter removal.

#### 16                               *Delivery System of the BI Filter*

17            Version 1 shown in **FIG. 3** may be used as the delivery system for the BI filter  
18    (including a biodegradable version) according to the present invention.

#### 19                               *Delivery of the BI Filter*

20            A preferably preformed guiding catheter or a guiding sheath (Balkin sheath-type)  
21    (**FIG. 3**) may be used for insertion of the delivery system for the embodiments discussed  
22    above. The BI filter may be secured to and stretched out on the surface of the delivery  
23    system in a manner described above, and may be delivered from the ipsilateral  
24    femoral/iliac vein through the caval junction into the contralateral iliac vein. As  
25    discussed above with regard to the delivery of the stents, the construction of the delivery  
26    system enables one to use a guidewire in the lumen of tube **22** for delivery of the filter,  
27    which is preferable in an exemplary embodiment of the present invention. It is to be

1 understood however, that a guidewire may not be utilized if a preformed sheath is in-  
2 place.

3 The BI filter may be delivered into place in the manner described above with  
4 regard to the delivery of the stents using version 1. All the advantages described above  
5 with regard to repositionability, *etc.*, apply equally to the delivery of the BI filter. In an  
6 exemplary embodiment of the delivery method for the BI filter, the distal end of the BI  
7 filter may be released first.

8 Advantageously, the BI filter according to the present invention may offer the  
9 possibility of a safe and successful thrombolysis, like the cava filters above discussed.

10 All of the methods and apparatus disclosed and claimed herein can be made and  
11 executed without undue experimentation in light of the present disclosure. While the  
12 methods and apparatus of the present invention have been described in terms of  
13 illustrative embodiments, it will be apparent to those of skill in the art that variations may  
14 be applied to apparatus and in the steps or in the sequence of steps of the methods  
15 described herein without departing from the concept, spirit and scope of the invention.  
16 More specifically, it will be apparent that certain agents which are both chemically and  
17 physiologically related may be substituted for the agents described herein while the same  
18 or similar results would be achieved. All such similar substitutes and modifications  
19 apparent to those skilled in the art are deemed to be within the spirit, scope and concept  
20 of the invention as defined by the appended claims.

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- 18

**WHAT IS CLAIMED IS:**

1. A device comprising:  
a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having first and second ends, the shape memory wires crossing each other to form a plurality of angles, at least one of the angles being obtuse, and both ends of at least one shape memory wire being located proximate one end of the body;  
wherein the value of the at least one obtuse angle may be increased by axially compressing the body.
2. The device of claim 1, wherein the shape memory wires comprise nitinol.
3. The device of claim 1, wherein the shape memory wires comprise FePt, FePd or FeNiCoTi.
4. The device of claim 1, wherein the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.
5. The device of claim 1, wherein the shape memory wires each have a diameter ranging in size from about 0.006 inches to about 0.012 inches.
6. The device of claim 1, wherein the plurality of shape memory wires includes at least 6 shape memory wires.
7. The device of claim 1, wherein the body has a tubular shape with a substantially uniform diameter.
8. The device of claim 1, wherein the body has a tapered shape with a diameter that decreases from one end of the body to the other end of the body.

- 1       9.     The device of claim 1, wherein the body has a generally hourglass shape.  
2
- 3       10.    The device of claim 1, wherein the body is hand woven.  
4
- 5       11.    The device of claim 1, wherein the body is machine woven.  
6
- 7       12.    The device of claim 1, further comprising a graft material attached to the body.  
8
- 9       13.    The device of claim 12, wherein the graft material comprises woven polyester.  
10
- 11      14.    The device of claim 12, wherein the graft material comprises Dacron.  
12
- 13      15.    The device of claim 12, wherein the graft material comprises polyurethane.  
14
- 15      16.    The device of claim 12, wherein the graft material comprises PTFE.  
16
- 17      17.    The device of claim 12, wherein the graft material partially covers the body.  
18
- 19      18.    The device of claim 1, further comprising:  
20           a first tube configured to accept a guide wire; and  
21           a second tube configured to fit over the first tube.  
22
- 23      19.    The device of claim 18, wherein the second tube is placed over the first tube, one  
24      end of the body is secured to the first tube and the other end of the body is secured to the  
25      second tube.  
26
- 27      20.    A device comprising:  
28           a body suitable for implantation into an anatomical structure, the body having a  
29           first end, a second end and being defined by at least n shape memory  
30           wires, wherein n is greater than one, the n shape memory wires being

1 arranged such that the body comprises a first portion, the first portion  
2 comprising a first woven portion and at least one strut, the shape memory  
3 wires of the first woven portion crossing each other to form a plurality of  
4 angles, at least one of the angles being obtuse, and both ends of at least  
5 one shape memory wire being located proximate one end of the body;  
6 wherein the value of the at least one obtuse angle may be increased by axially  
7 compressing the body.  
8

9 21. The device of claim 20, wherein the shape memory wires comprise nitinol.

10  
11 22. The device of claim 20, wherein the shape memory wires comprise FePt, FePd or  
12 FeNiCoTi.

13  
14 23. The device of claim 20, wherein the shape memory wires comprise FeNiC,  
15 FeMnSi or FeMnSiCrNi.

16  
17 24. The device of claim 20, wherein the body further comprises a second portion  
18 adjacent the first portion, the second portion comprising a second woven portion, and the  
19 second portion having  $n + x$  shape memory wires, wherein  $x$  is at least one.

20  
21 25. The device of claim 20, wherein the first portion comprises a first woven portion  
22 separated from a second woven portion by multiple first struts.

23  
24 26. The device of claim 25, wherein the first portion has a generally domed shape.

25  
26 27. The device of claim 25, wherein the first woven portion has a generally domed  
27 shape and the multiple first struts are bent slightly so as to increase the self-anchoring  
28 capability of the body in an anatomical structure.  
29

- 1 28. The device of claim 25, wherein the first portion further comprises a third woven  
2 portion separated from the second woven portion by multiple second struts, and wherein  
3 the first and third woven portions have generally domed shapes.  
4
- 5 29. The device of claim 20, further comprising a graft material attached to the body.  
6
- 7 30. The device of claim 29, wherein the graft material comprises woven polyester.  
8
- 9 31. The device of claim 29, wherein the graft material comprises Dacron.  
10
- 11 32. The device of claim 29, wherein the graft material comprises polyurethane.  
12
- 13 33. The device of claim 29, wherein the graft material comprises PTFE.  
14
- 15 34. The device of claim 29, wherein the graft material partially covers the body.  
16
- 17 35. The device of claim 20, further comprising:  
18 a first tube configured to accept a guide wire; and  
19 a second tube configured to fit over the first tube.  
20
- 21 36. The device of claim 35, wherein the second tube is placed over the first tube, one  
22 end of the body is secured to the first tube and the other end of the body is secured to the  
23 second tube.  
24
- 25 37. A device comprising:  
26 a plurality of biodegradable filaments woven together to form a self-expanding  
27 body suitable for implantation into an anatomical structure, the self-  
28 expanding body having first and second ends, the biodegradable filaments  
29 crossing each other to form a plurality of angles, at least one of the angles  
30 being obtuse;

1           wherein the value of the at least one obtuse angle may be increased by axially  
2           compressing the self-expanding body.

3  
4       38.    A method of creating a body suitable for implantation into an anatomical  
5       structure, the body having two ends, the method comprising:

6           bending the shape memory wires in a plurality of shape memory wires to create  
7           bent portions in the shape memory wires, the bent portions being arranged  
8           to define one end of the body, each shape memory wire having two ends;  
9           and

10          weaving the ends of the shape memory wires to create the body such that the  
11          shape memory wires cross each other to form a plurality of angles, at least  
12          one of the angles being obtuse;

13          wherein the value of the at least one obtuse angle may be increased by axially  
14          compressing the body.

15  
16       39.    The method of claim 38, wherein the bent portions are bends.

17  
18       40.    The method of claim 38, wherein the bent portions are loops.

19  
20       41.    The method of claim 38, wherein the shape memory wires comprise nitinol.

21  
22       42.    The method of claim 38, wherein the shape memory wires comprise FePt, FePd or  
23       FeNiCoTi.

24  
25       43.    The method of claim 38, wherein the shape memory wires comprise FeNiC,  
26       FeMnSi or FeMnSiCrNi.

27  
28       44.    The method of claim 38, wherein the shape memory wires each have a diameter  
29       ranging in size from about 0.006 inches to about 0.012 inches.

30

1 45. The method of claim 38, wherein the plurality of shape memory wires includes at  
2 least 6 shape memory wires.

3  
4 46. The method of claim 38, wherein the body has a tubular shape with a substantially  
5 uniform diameter.

6  
7 47. The method of claim 38, wherein the body has a tapered shape with a diameter  
8 that decreases from one end of the body to the other end of the body.

9  
10 48. The method of claim 38, wherein the body has a generally hourglass shape.

11  
12 49. The method of claim 38, wherein the weaving is by hand.

13  
14 50. The method of claim 38, wherein the weaving is by machine.

15  
16 51. A method of creating a body suitable for implantation into an anatomical  
17 structure, the body having two ends, the method comprising:

18 providing a weaving system comprising:

19 a template having first template projections;

20 bending shape memory wires around the first template projections to create bent  
21 portions in the shape memory wires, the bent portions being arranged to

22 define one end of the body, each shape memory wire having two ends; and

23 weaving the ends of the shape memory wires around the template to create the

24 body such that the shape memory wires cross each other to form a plurality

25 of angles, at least one of the angles being obtuse;

26 wherein the value of the at least one obtuse angle may be increased by axially  
27 compressing the body.

28  
29 52. The method of claim 51, wherein the first template projections comprise tabs.



1 53. The method of claim 51, wherein the first template projections comprise pins.

2

3 54. The method of claim 53, wherein the pins are attached to a ring engaged with the  
4 template.

5

6 55. The method of claim 51, wherein the weaving system further comprises a first  
7 weaving plate configured to rotate in a first direction during the weaving.

8

9 56. The method of claim 55, wherein the weaving system further comprises first  
10 bobbins arranged on the first weaving plate, one end of each shape memory wire being  
11 attached to each first bobbin prior to the weaving.

12

13 57. The method of claim 55, wherein the weaving system further comprises a second  
14 weaving plate configured to rotate in a second direction during the weaving, the second  
15 weaving plate being spaced apart from the first weaving plate.

16

17 58. The method of claim 57, wherein the weaving system further comprises second  
18 bobbins arranged on the second weaving plate, one end of each shape memory wire being  
19 attached to each second bobbin prior to the weaving.

20

21 59. The method of claim 51, further comprising securing the shape memory wires to  
22 the template.

23

24 60. The method of claim 51, further comprising forming closed structures with the  
25 ends of the shape memory wires, the closed structures being arranged to define the other  
26 end of the body.

27

28 61. The method of claim 51, further comprising heating the body and the template.

29

1       62.     A device for delivering an axially and radially expandable woven body having  
2       two ends into an anatomical structure, comprising:

3             a first tube configured to accept a guide wire; and

4             a second tube configured to fit over the first tube;

5       wherein when the tubes are used for delivering the axially and radially expandable  
6       woven body, one end of the axially and radially expandable woven body is  
7       secured to the outside of the first tube and the other end of the axially and  
8       radially expandable woven body is secured to the outside of the second  
9       tube.

10  
11       63.     The device of claim 62, further comprising a guide wire configured to be placed  
12       within the first tube.

13  
14       64.     The device of claim 62, further comprising a push-button release/lock mechanism  
15       configured to secure the first tube to the second tube.

16  
17       65.     The device of claim 62, further comprising an end fitting having a side arm, the  
18       end fitting being configured to be secured to the first tube.

19  
20       66.     A device for delivering an axially and radially expandable woven body having  
21       two ends into an anatomical structure, comprising:

22             a first tube configured to accept a guide wire, the first tube having at least one pair  
23             of first tube holes positioned proximate one end of the first tube;

24             a second tube configured to fit over the first tube, the second tube having at least  
25             one pair of second tube holes positioned proximate one end of the second  
26             tube;

27             a first securing wire configured to be threaded through the at least one pair of first  
28             tube holes; and

29             a second securing wire configured to be threaded through the at least one pair of  
30             second tube holes;

1 wherein when the tubes are used for delivering the axially and radially expandable  
2 woven body, one end of the axially and radially expandable woven body is  
3 secured to the outside of the first tube with the first securing wire and the  
4 other end of the axially and radially expandable woven body is secured to  
5 the outside of the second tube with the second securing wire.  
6

7 67. An occluding system comprising:

8 a plurality of shape memory wires woven together to form a body useful for  
9 occluding an anatomical structure, the body having first and second ends,  
10 both ends of at least one shape memory wire being located proximate one  
11 end of the body, the shape memory wires crossing each other to form a  
12 plurality of angles, at least one of the angles being obtuse;

13 wherein the value of the at least one obtuse angle may be increased by axially  
14 compressing the body.  
15

16 68. A device comprising:

17 a body suitable for implantation into an anatomical structure, the body having an  
18 axis, a first end and a second end, wherein the body comprises a shape  
19 memory wire having a first segment and a second segment, the segments  
20 being separated by a bend in the shape memory wire located proximate  
21 one end of the body, the first segment extending helically in a first  
22 direction around the axis toward the other end of the body, the second  
23 segment extending helically in a second direction around the axis toward  
24 the other end of the body, and the first and second segments crossing each  
25 other in a plurality of locations.  
26

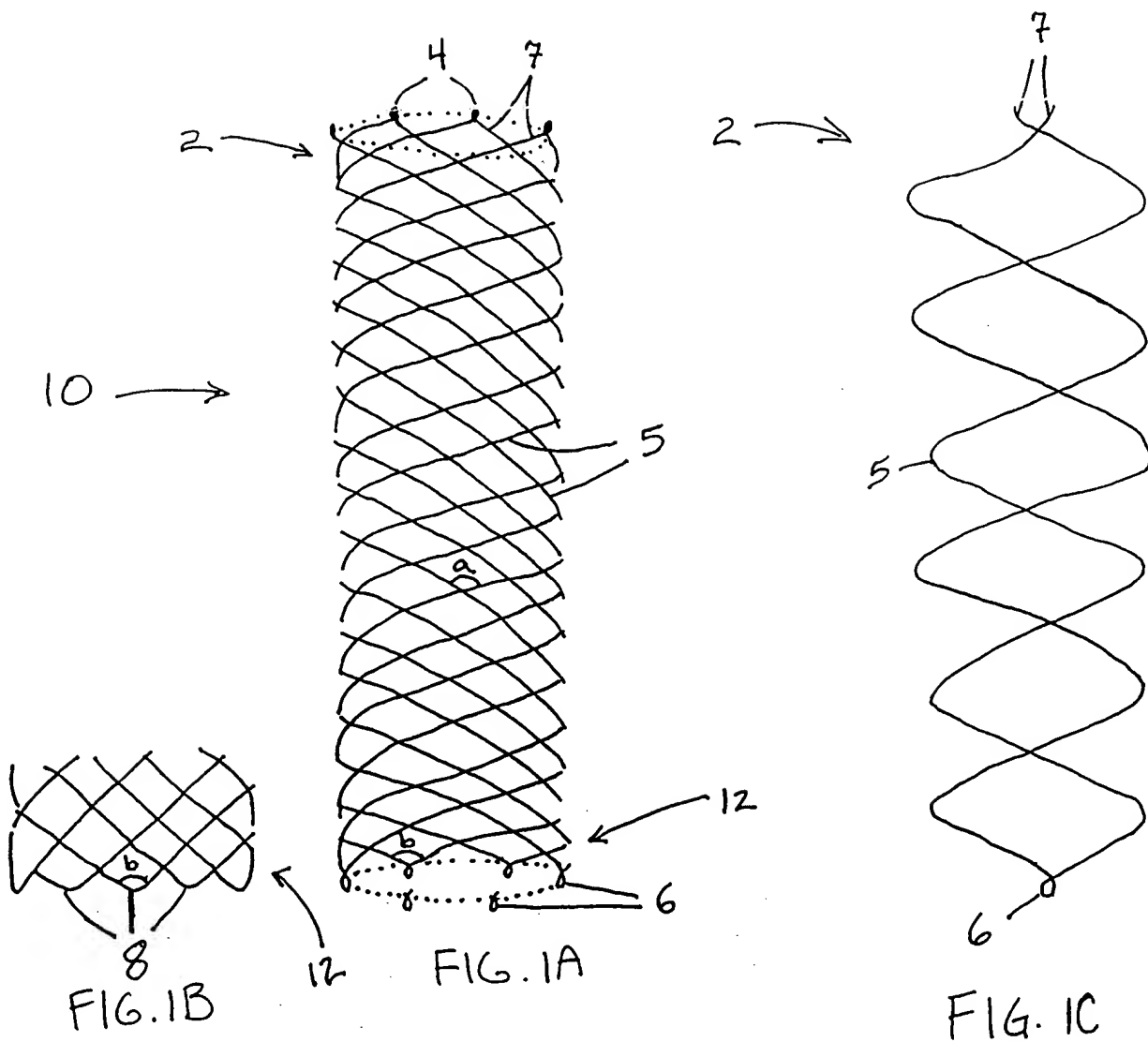
27 69. A device comprising:

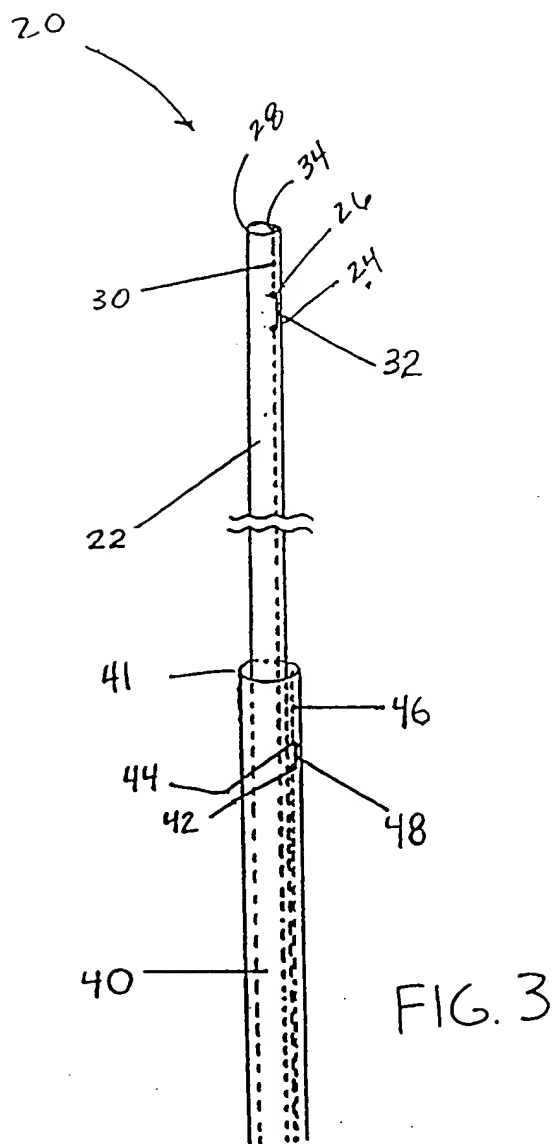
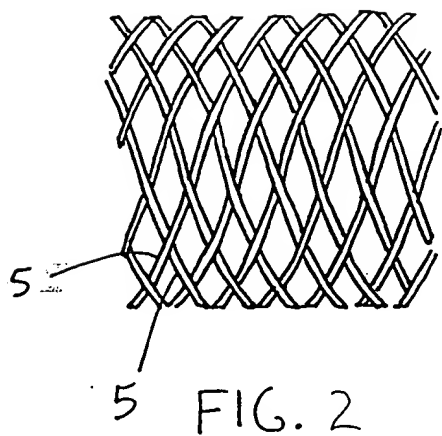
28 a body suitable for implantation into an anatomical structure, the body having a  
29 first end and a second end, wherein the body comprises a shape memory  
30 wire having a first segment and a second segment, the segments being

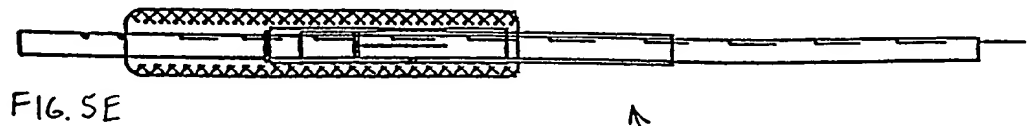
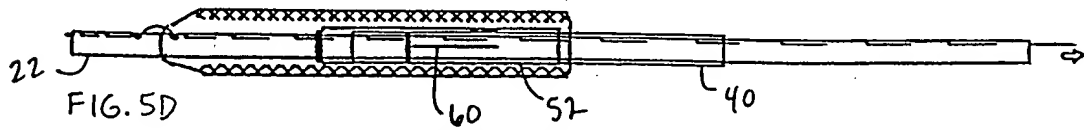
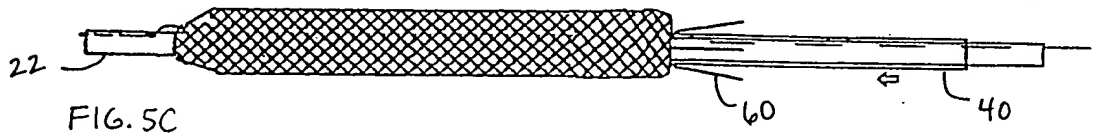
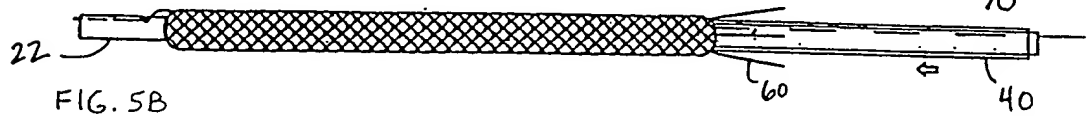
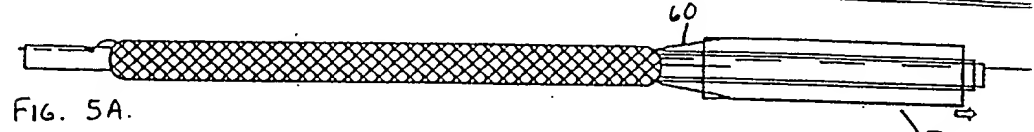
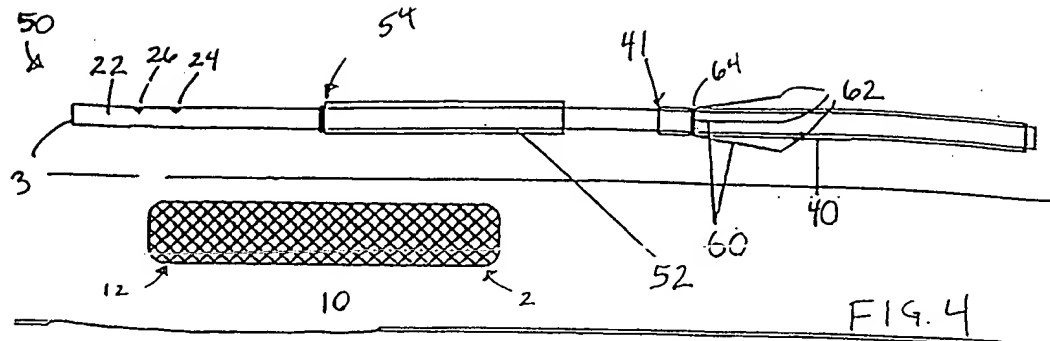
1                    separated by a bend in the wire located proximate one end of the body, the  
2                    first segment and second segments being arranged to form loops and  
3                    twisted segments such that at least two contiguous loops are separated  
4                    from another loop by a twisted segment.

5  
6        70.    A device comprising:

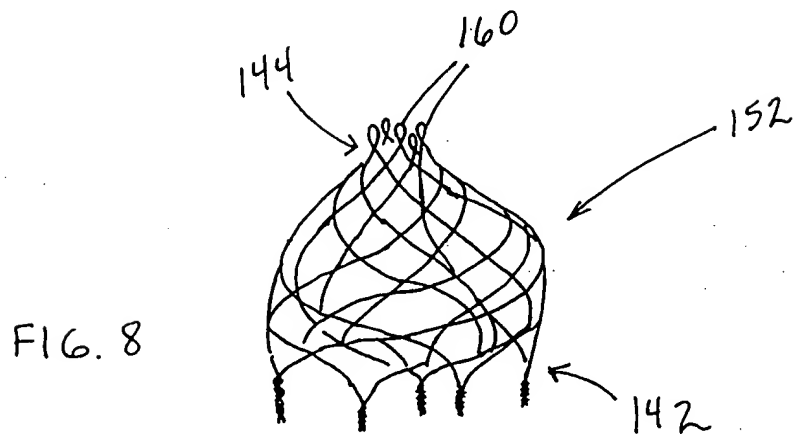
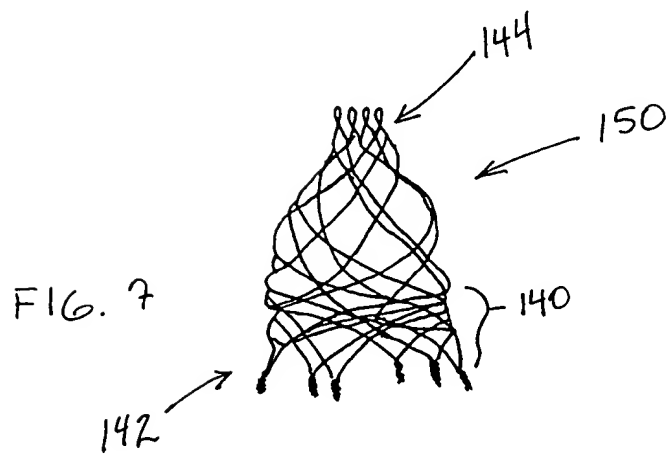
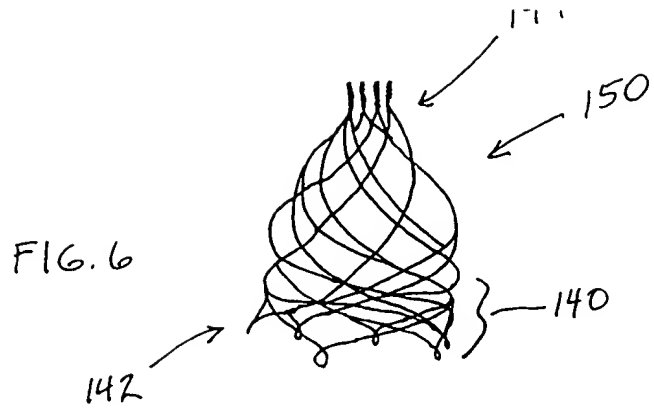
7                    a body suitable for implantation into an anatomical structure, the body having two  
8                    ends and comprising a shape memory wire having a first segment and a  
9                    second segment, the segments being separated by a bend in the wire  
10                   located proximate one end of the body, the segments being positioned  
11                   adjacent to each other in loop-defining locations, the segments also  
12                   extending between the loop-defining locations in spaced relation to each  
13                   other so as form at least two loops, at least one of the at least two loops  
14                   having a compressed shape.







50





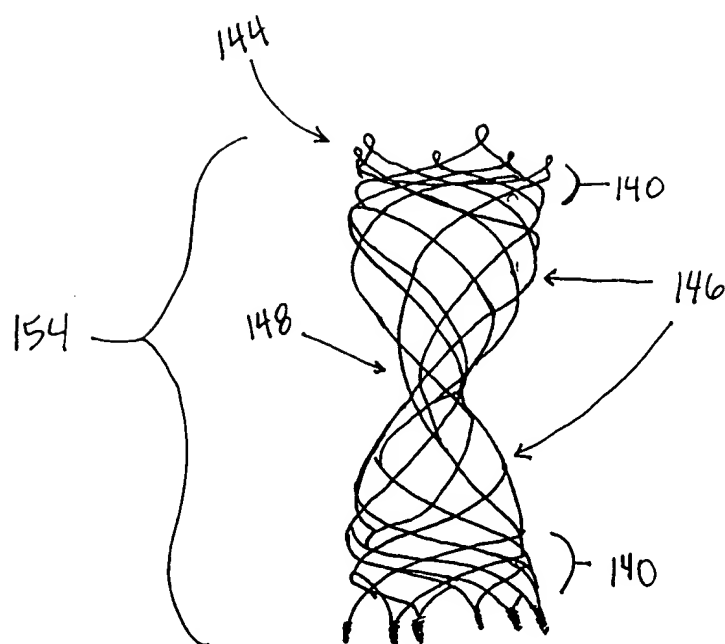
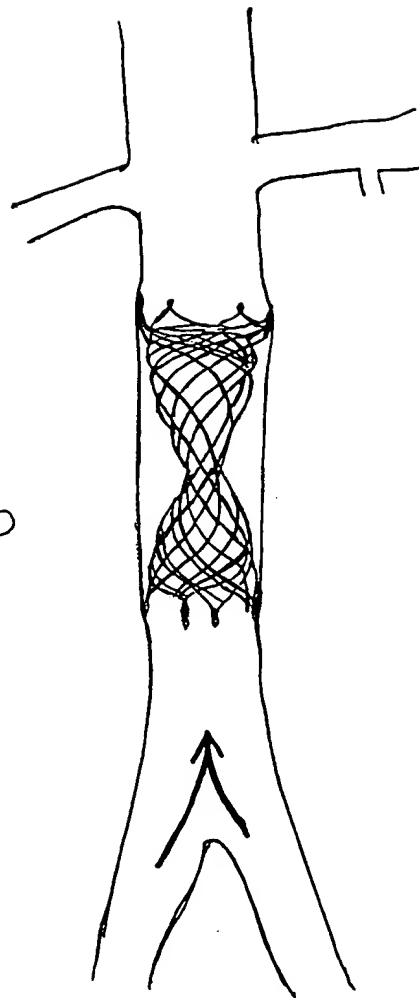
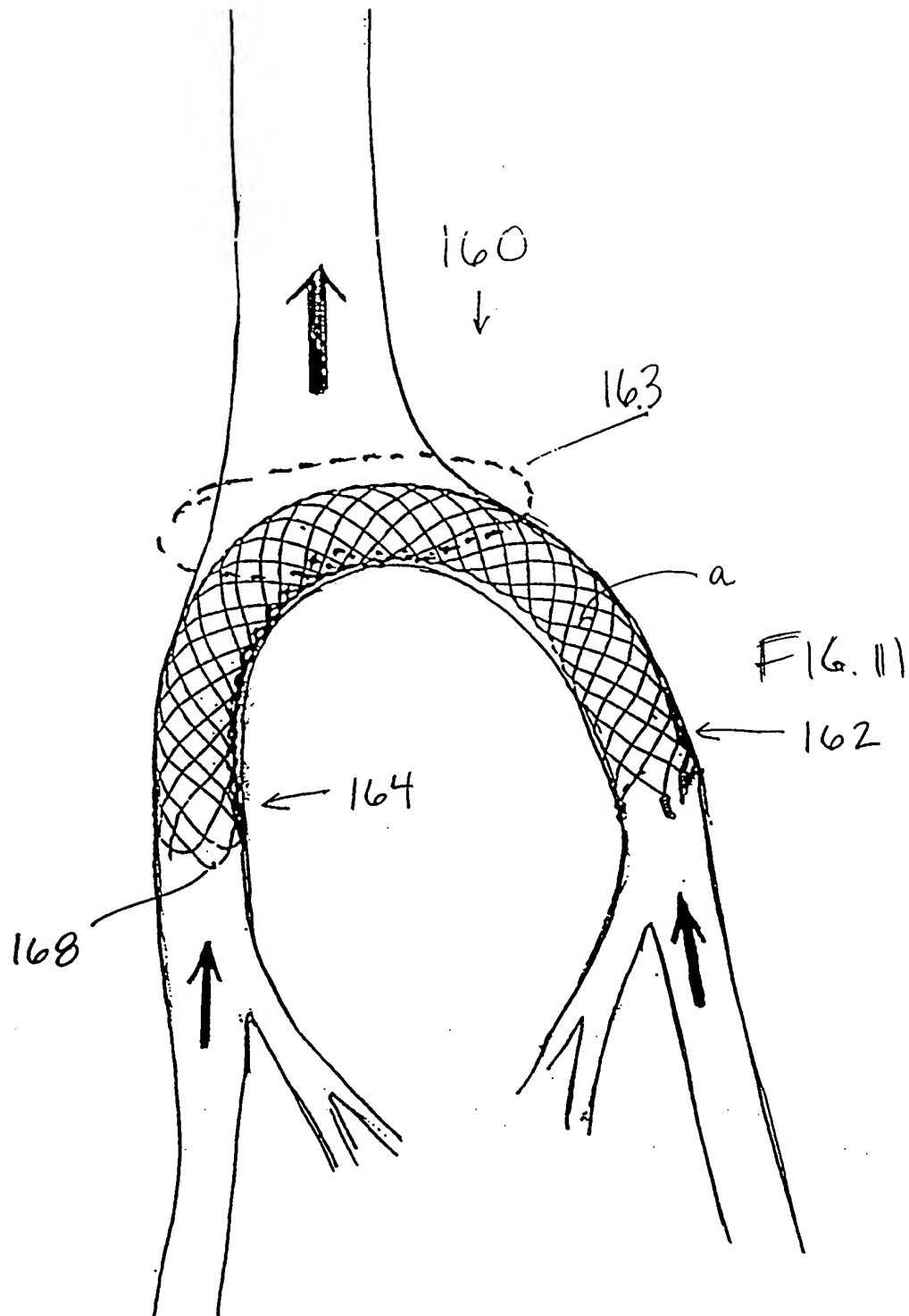
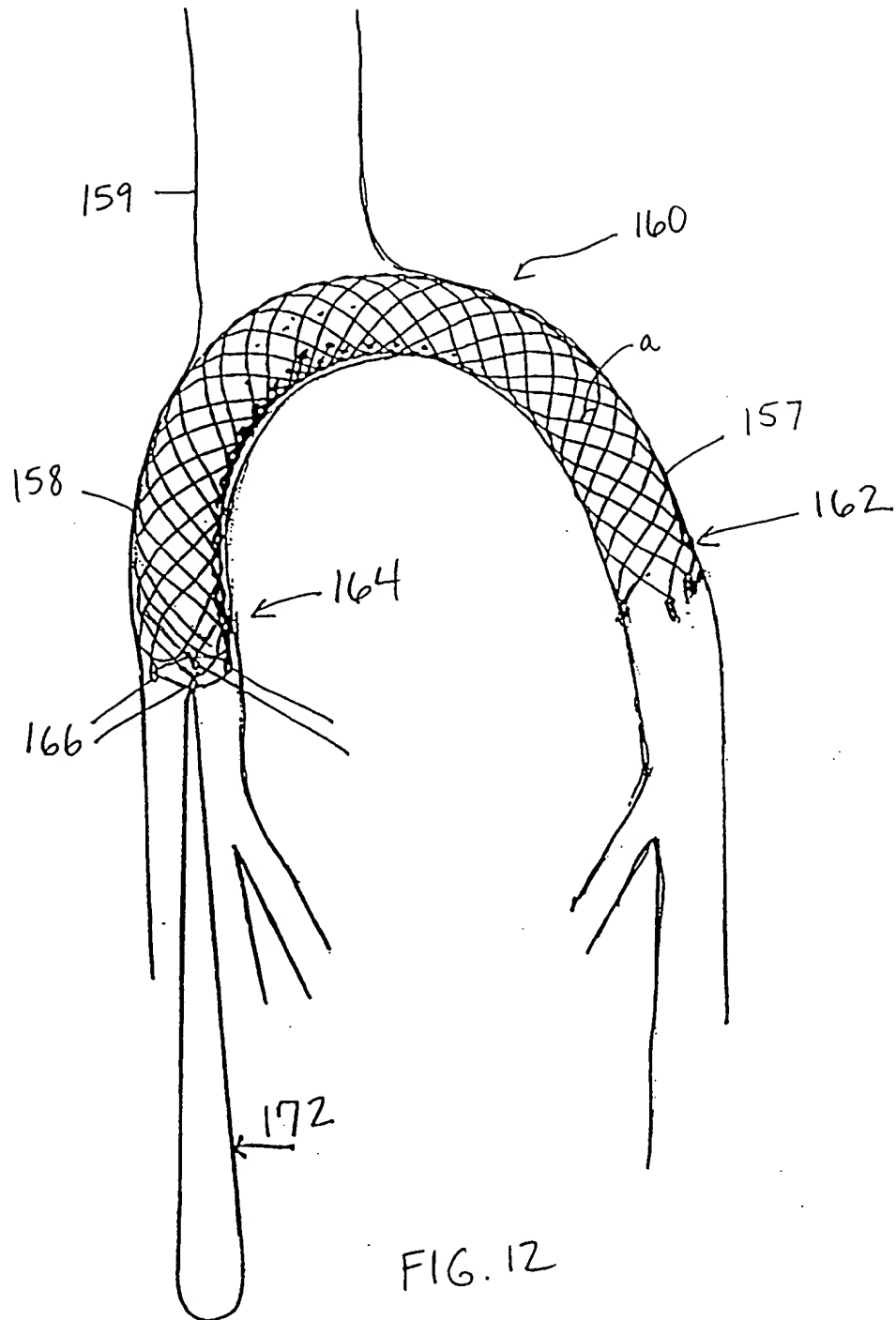


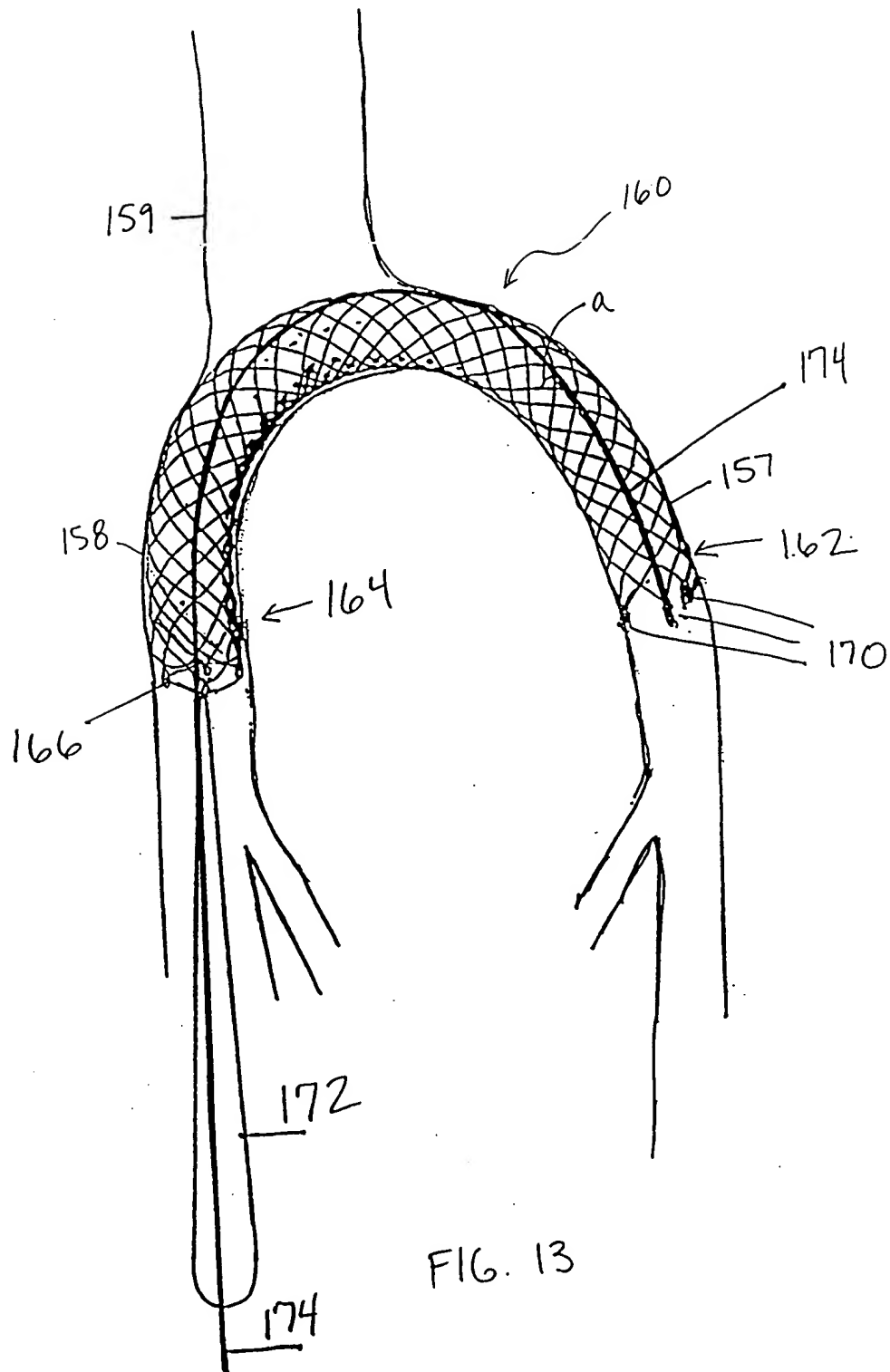
FIG. 9

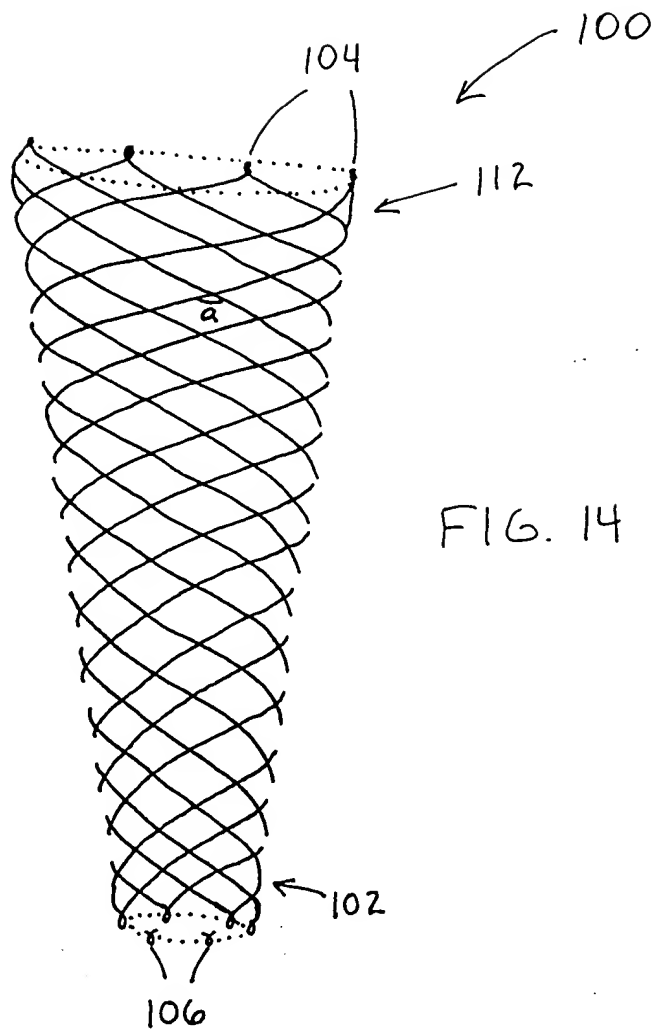
FIG. 10











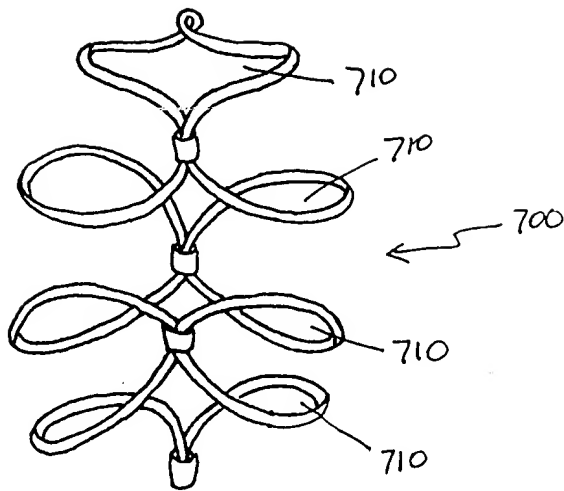


FIG. 15

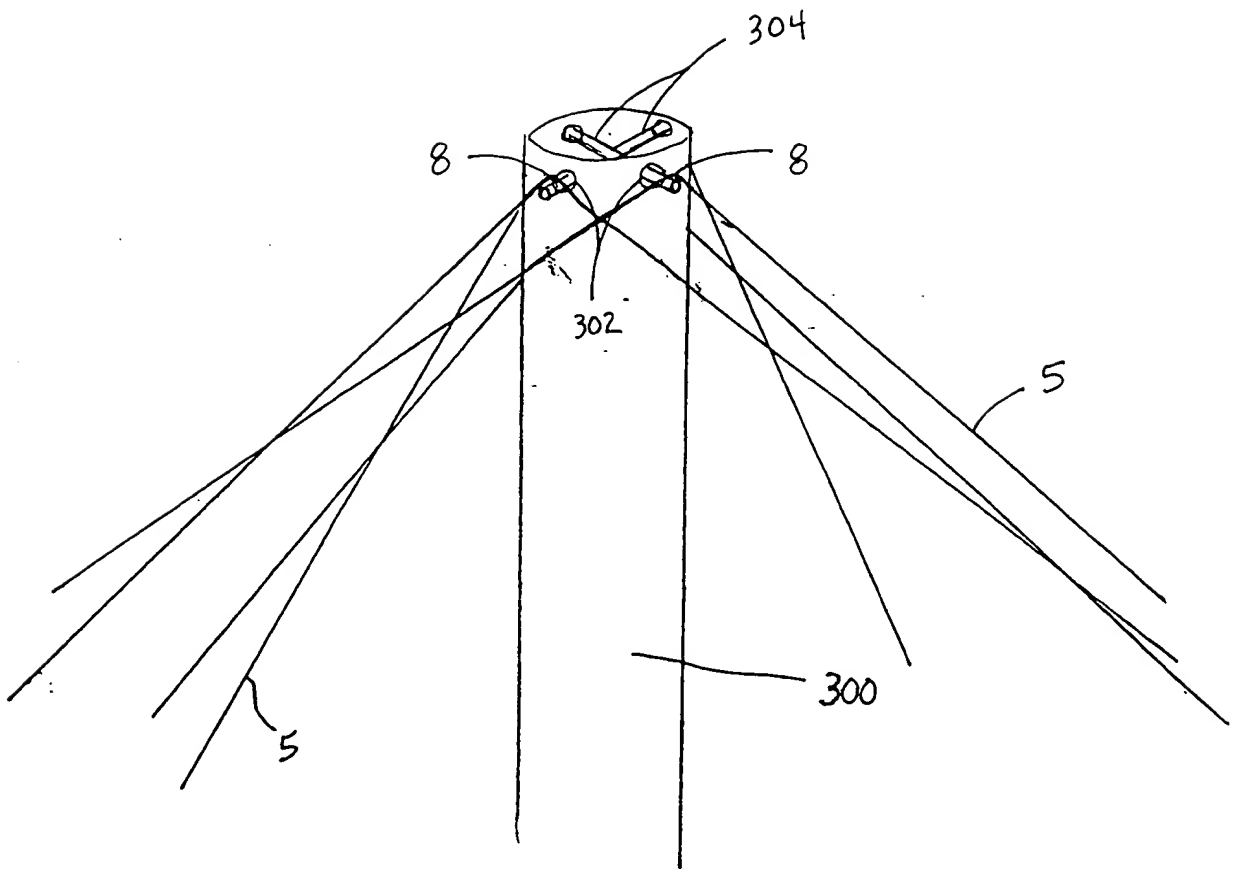


FIG. 16



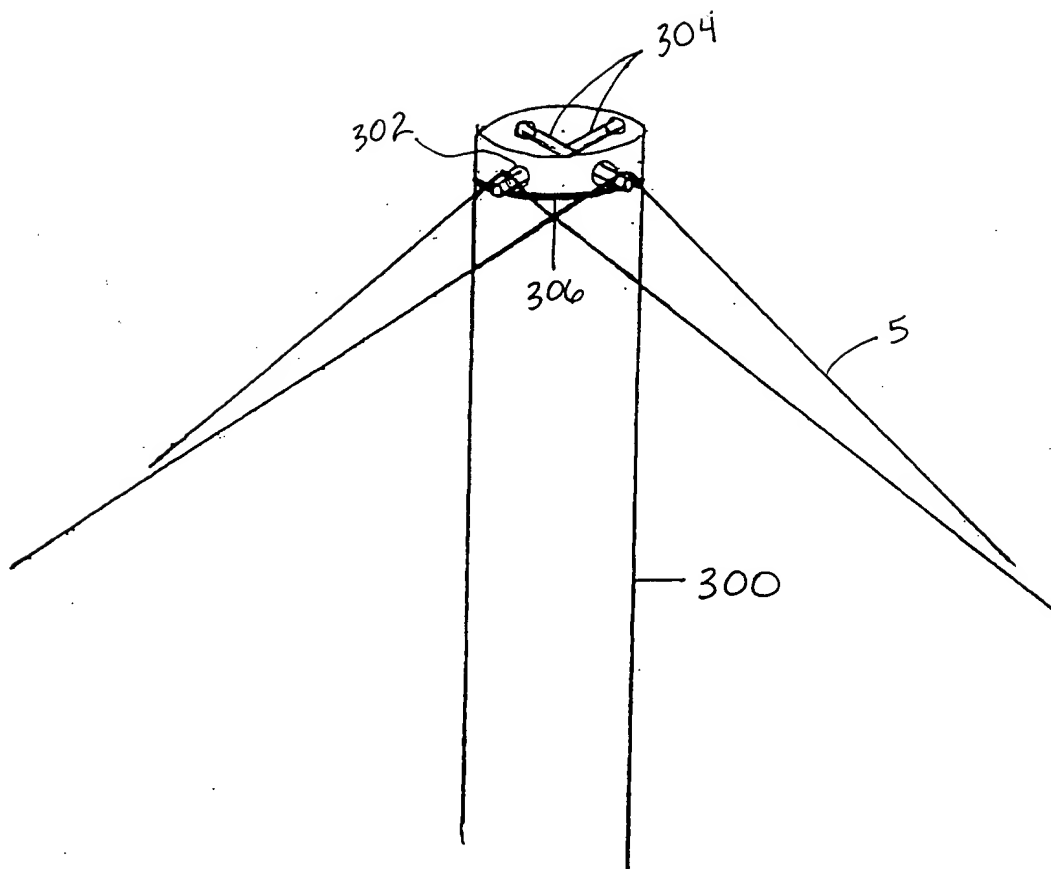
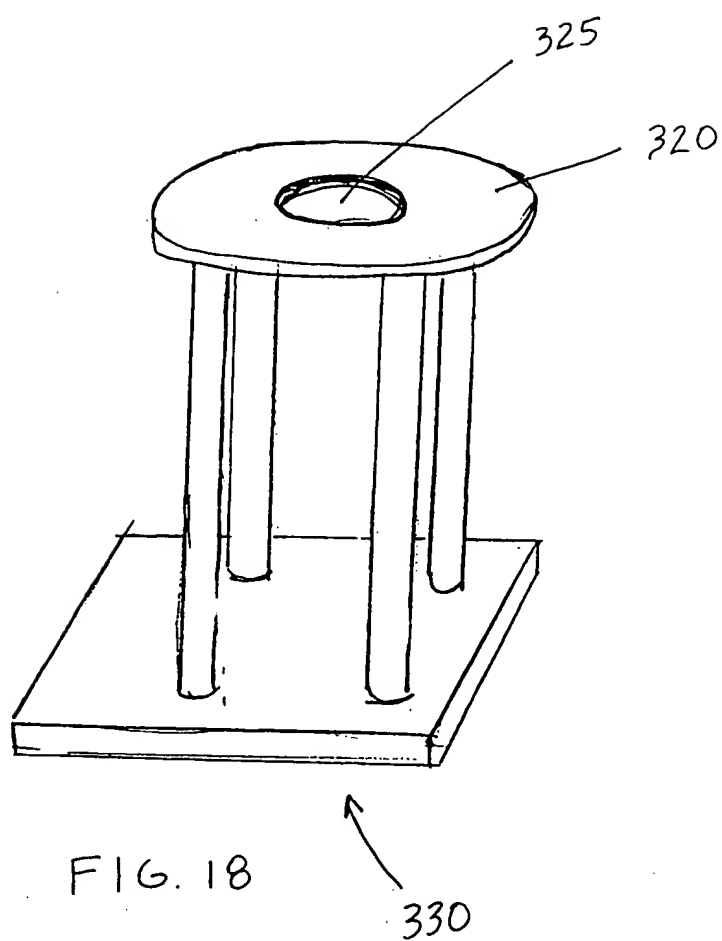
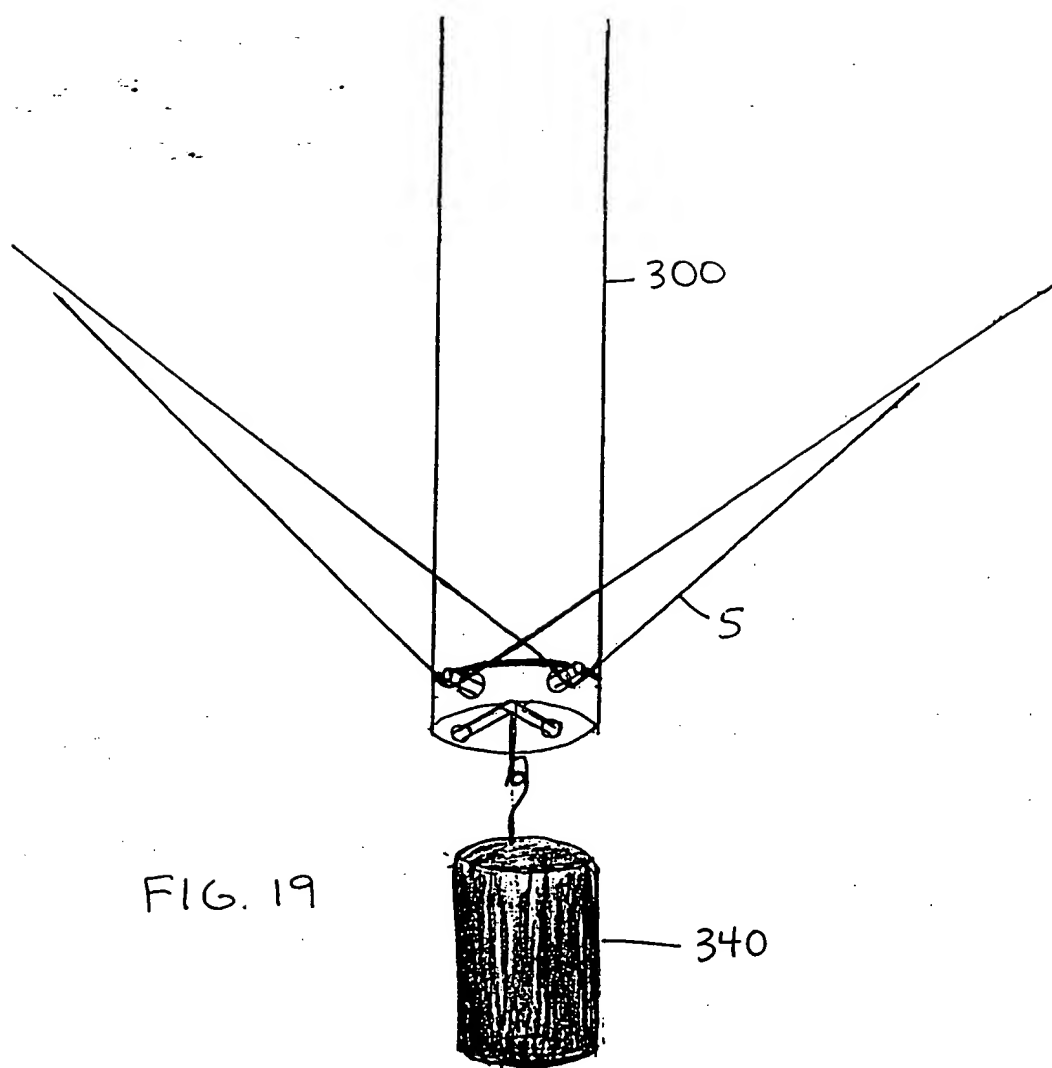


FIG. 17





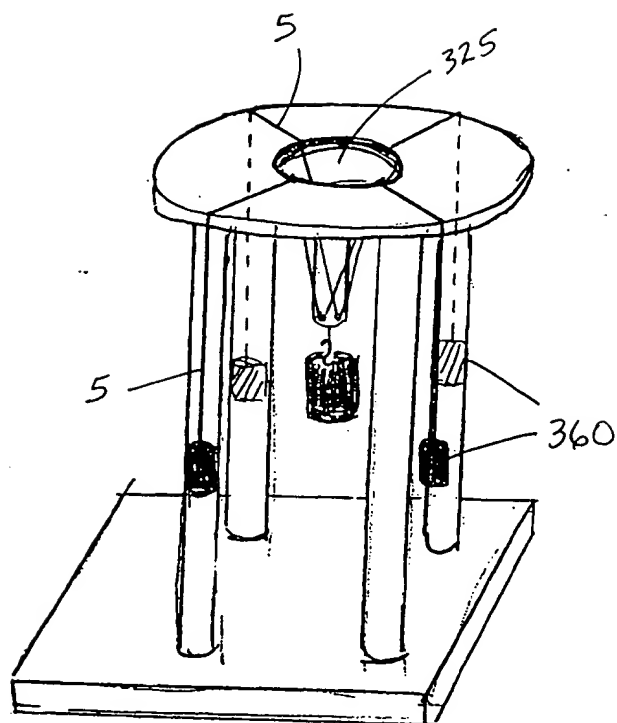


FIG. 20

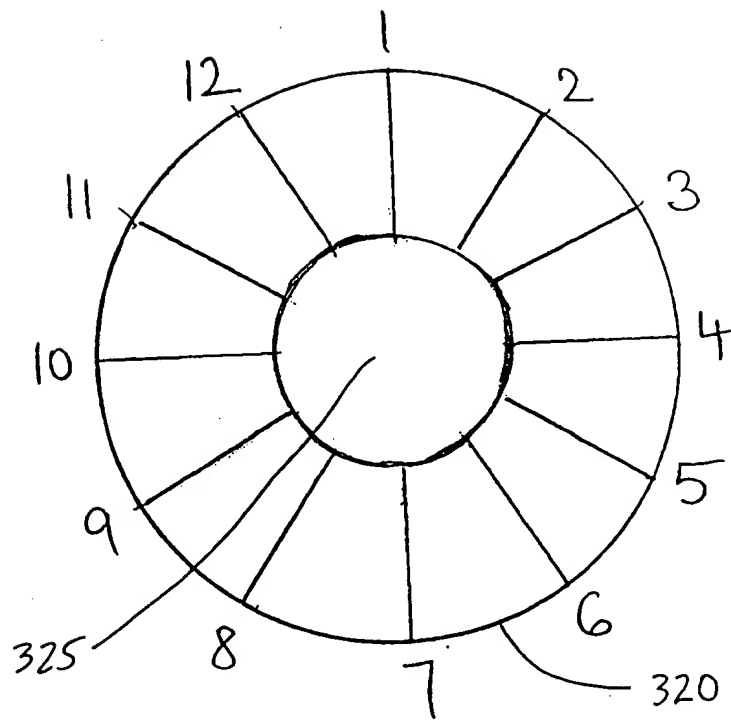
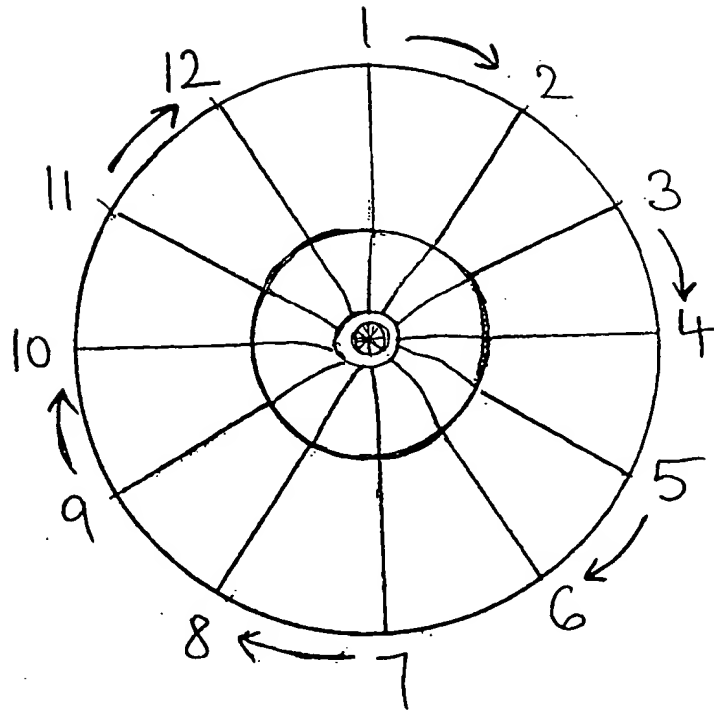
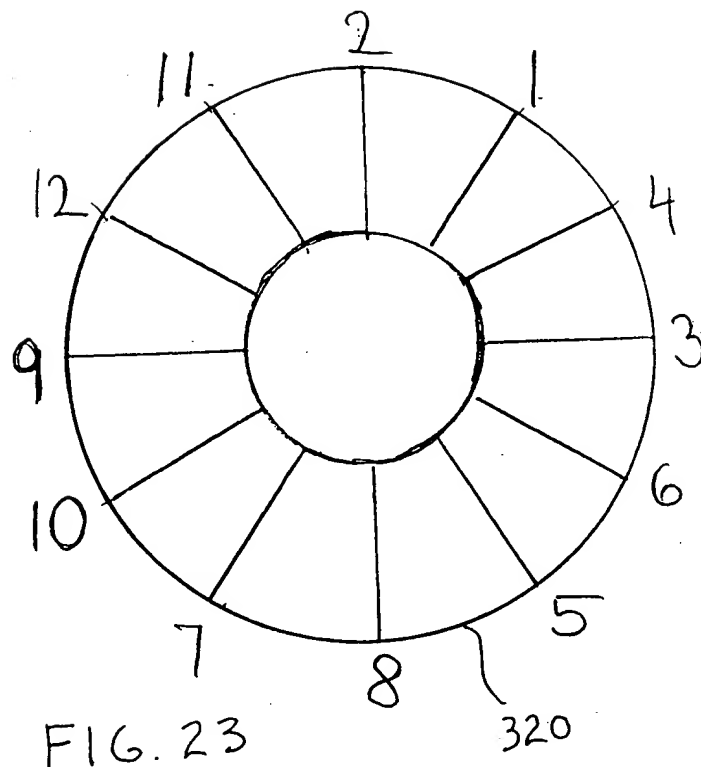


FIG. 21

FIG. 22





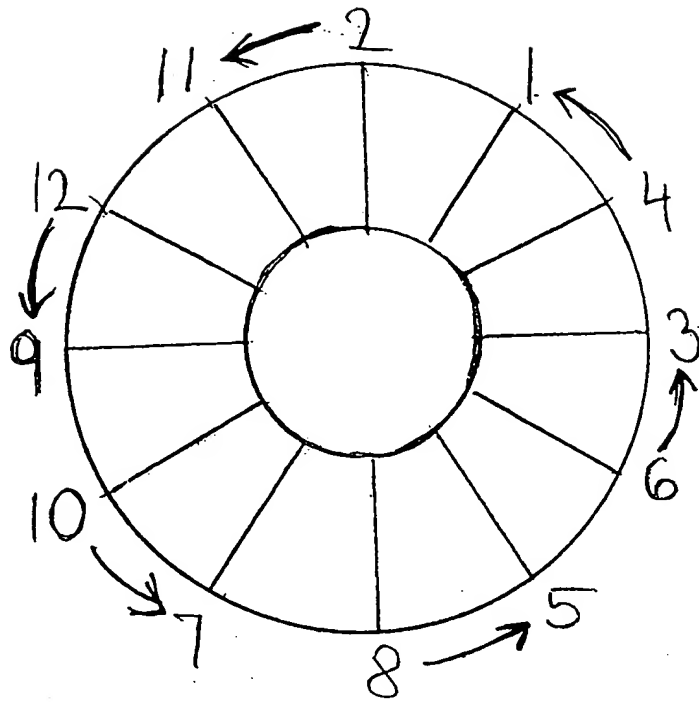
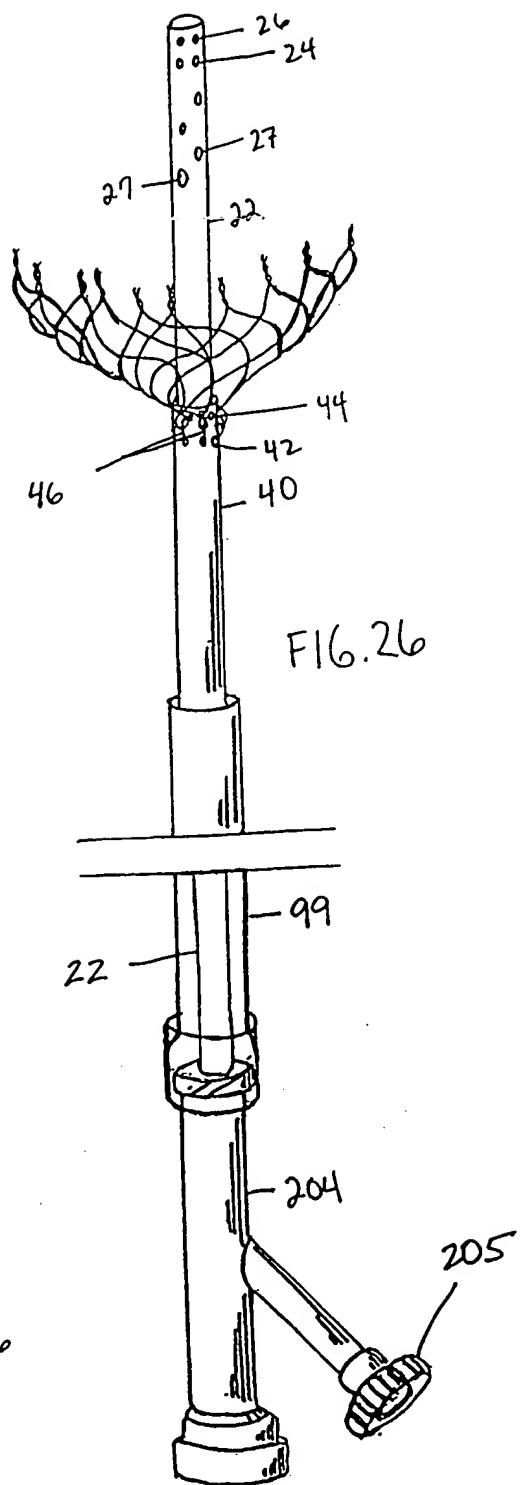
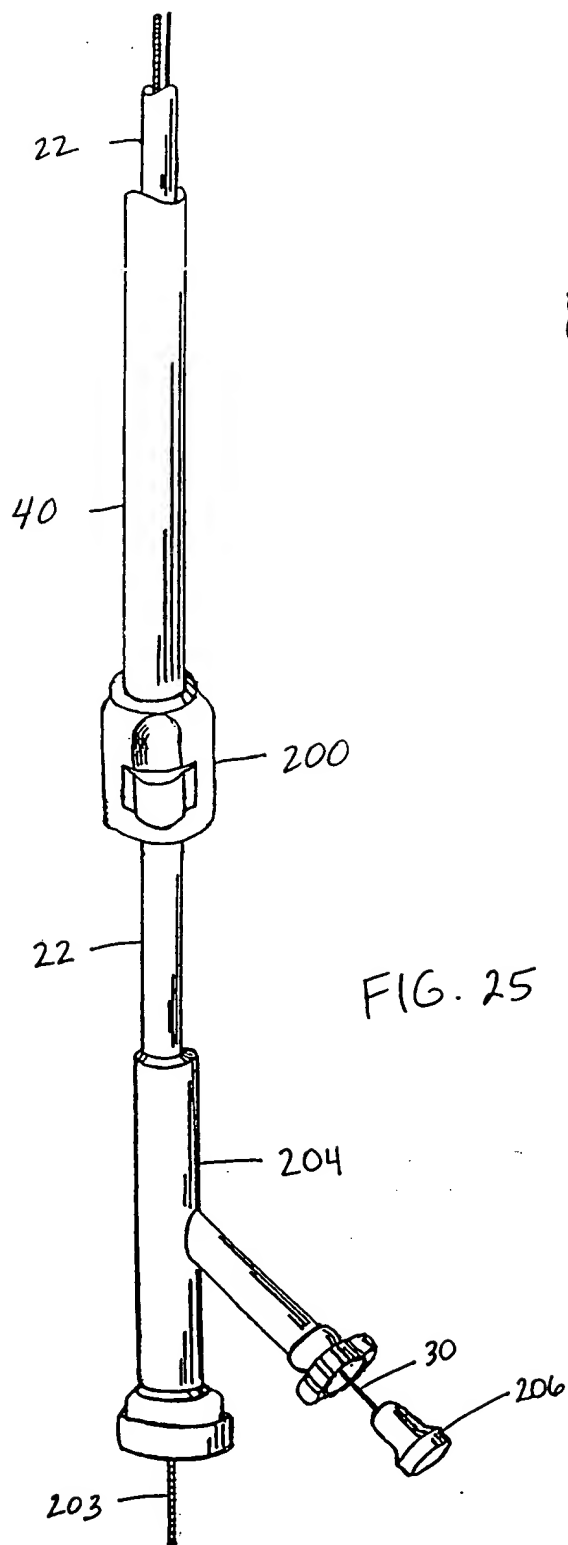


FIG. 24





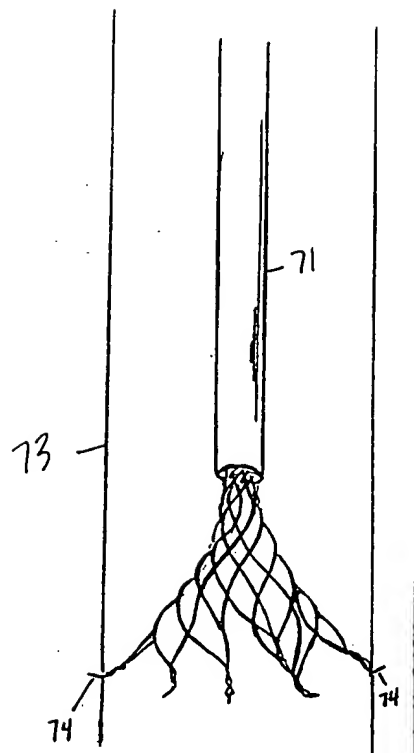


FIG. 27A

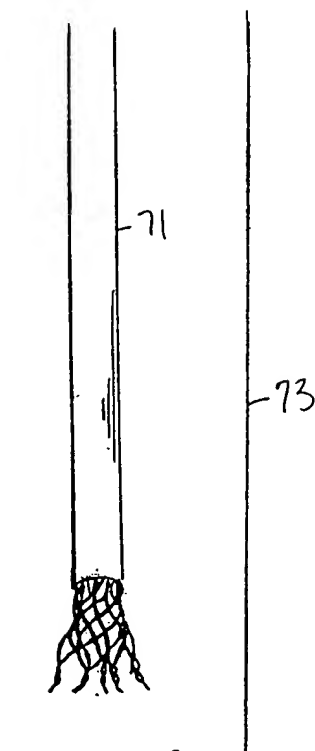


FIG. 27B

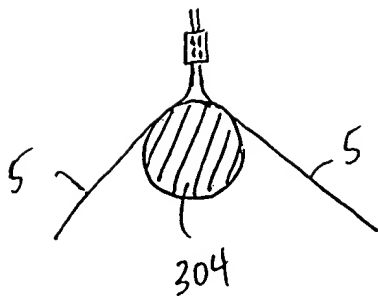
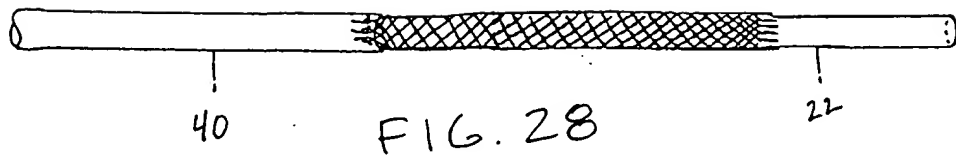


FIG. 30A

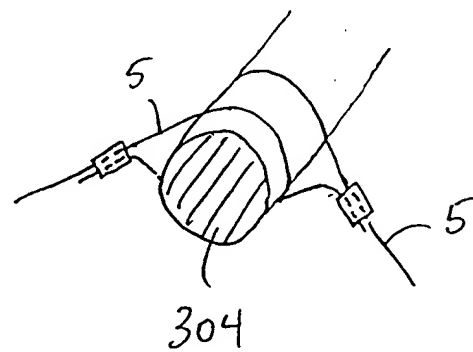


FIG. 30B

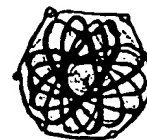


FIG. 29

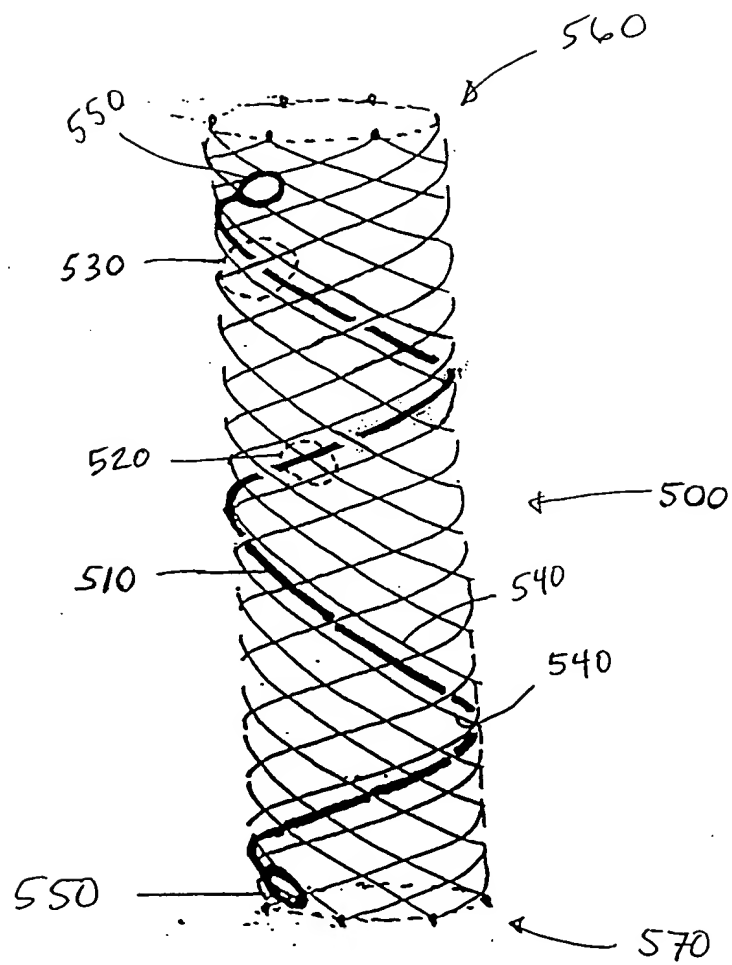


FIG. 31

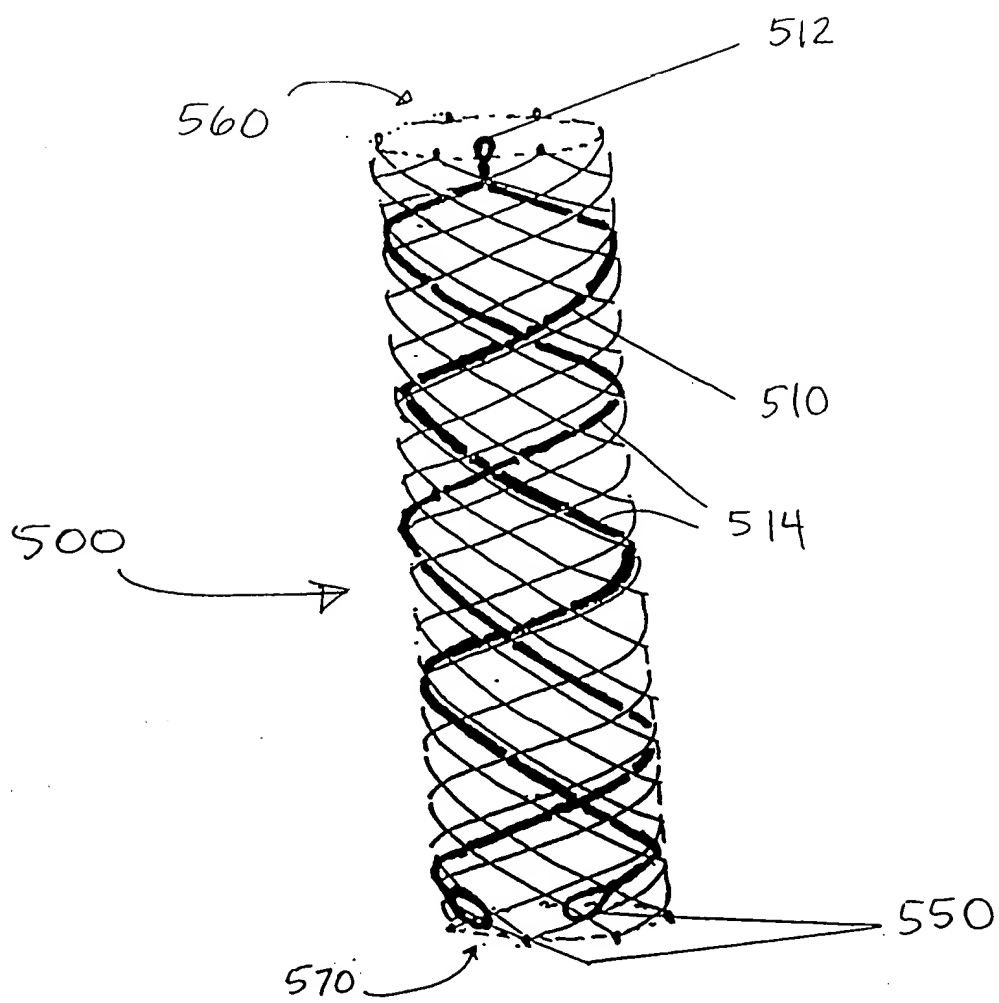
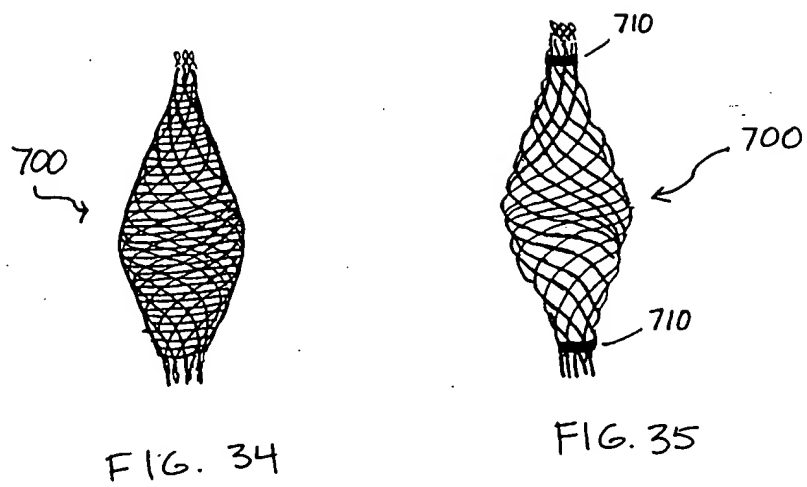
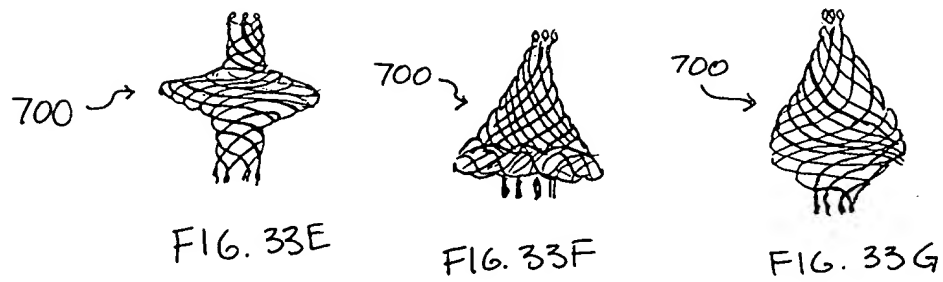
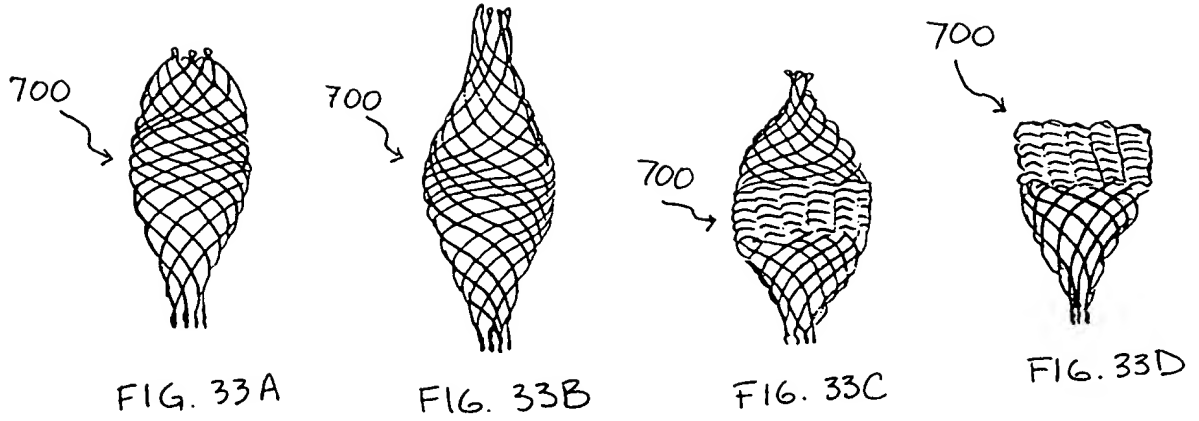


FIG. 32



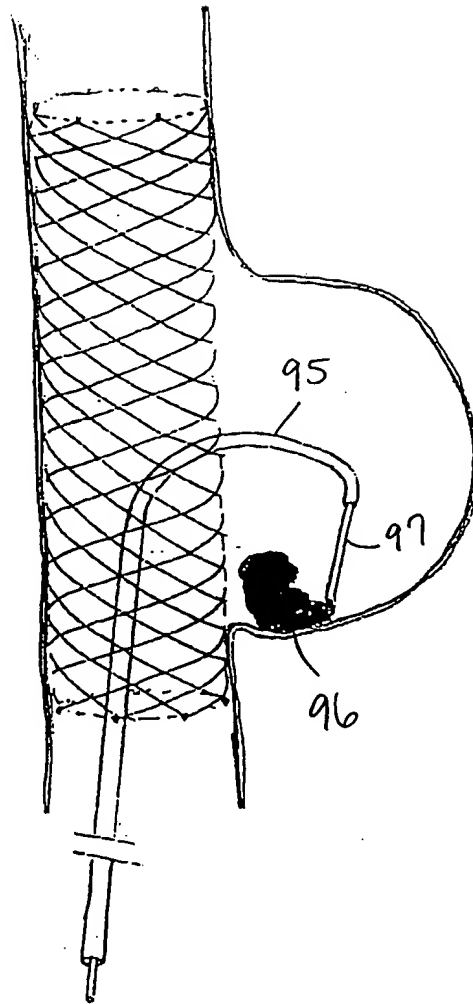


FIG. 36

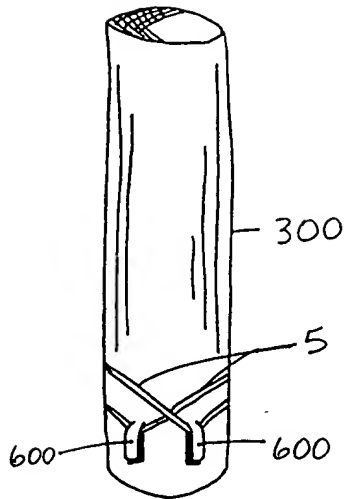


FIG. 37

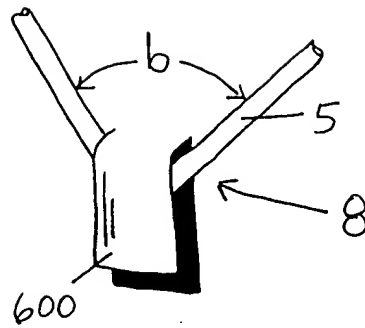


FIG. 38A

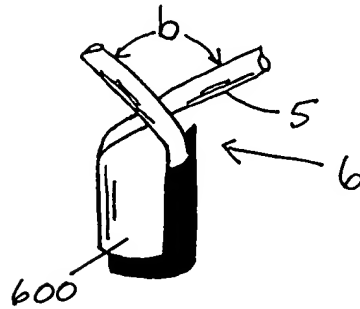


FIG. 38B

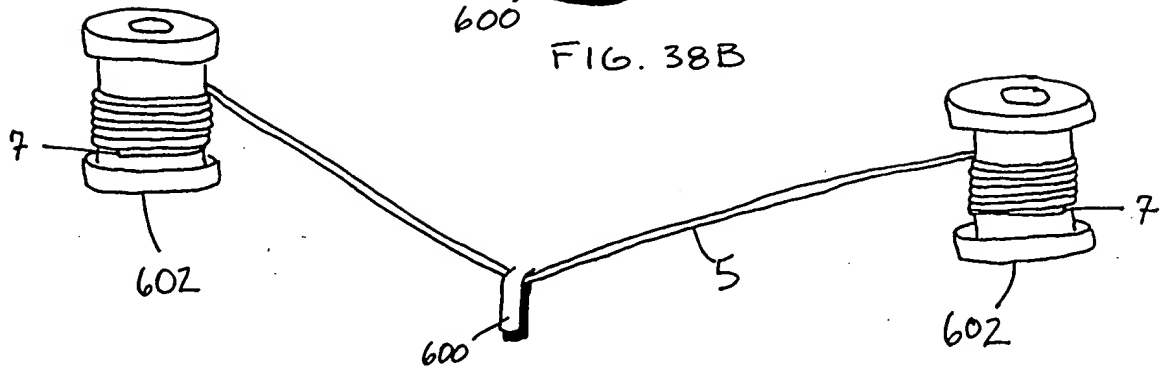


FIG. 39



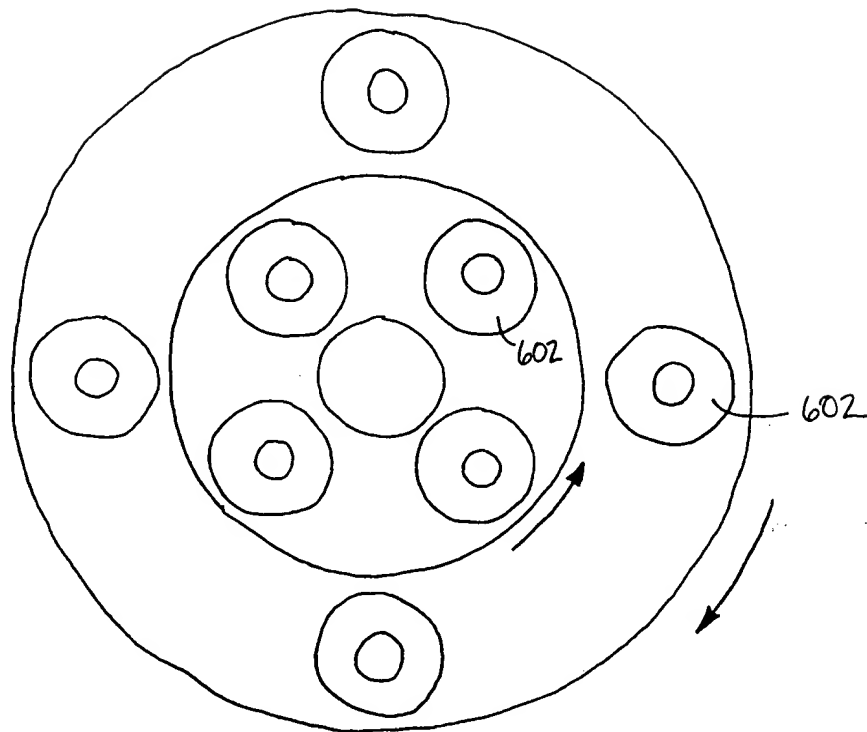
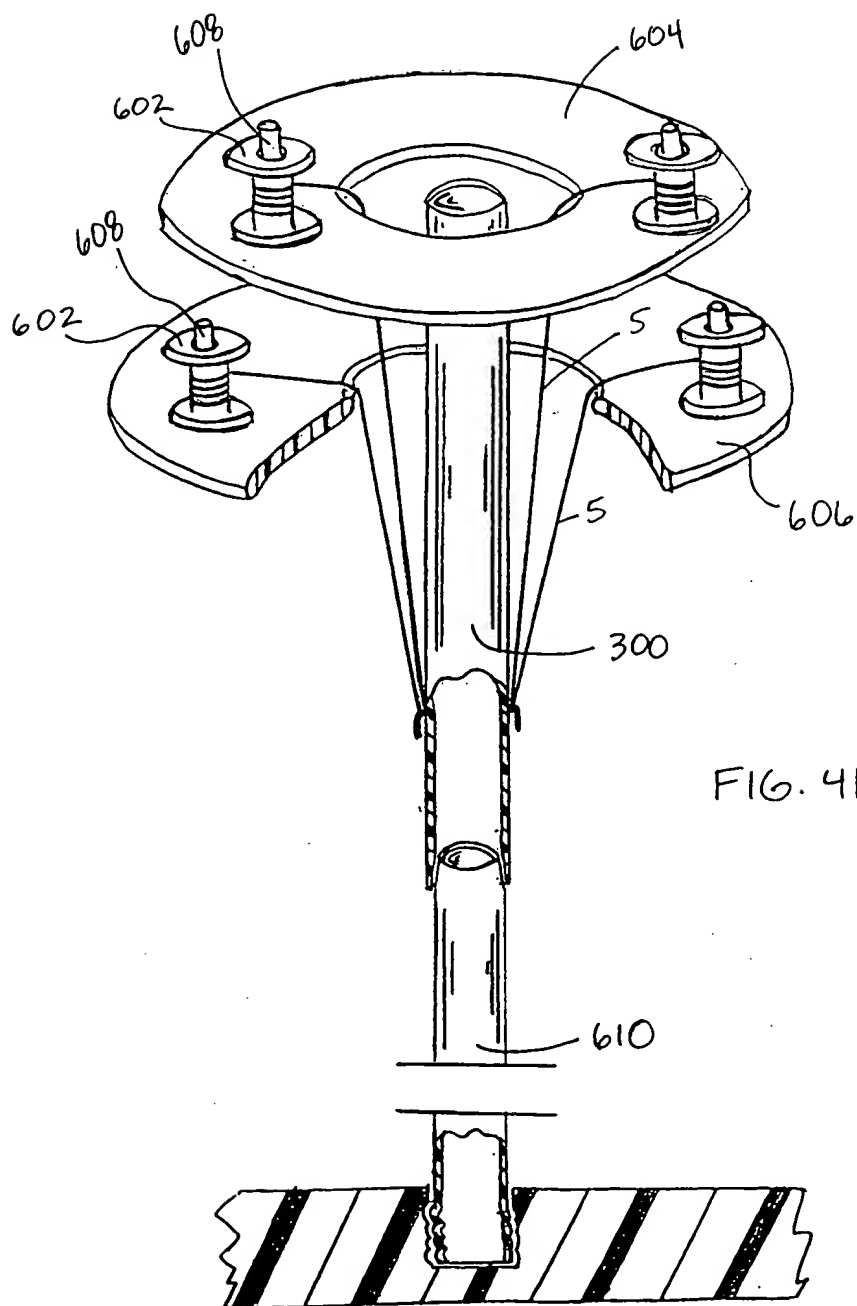


FIG. 40



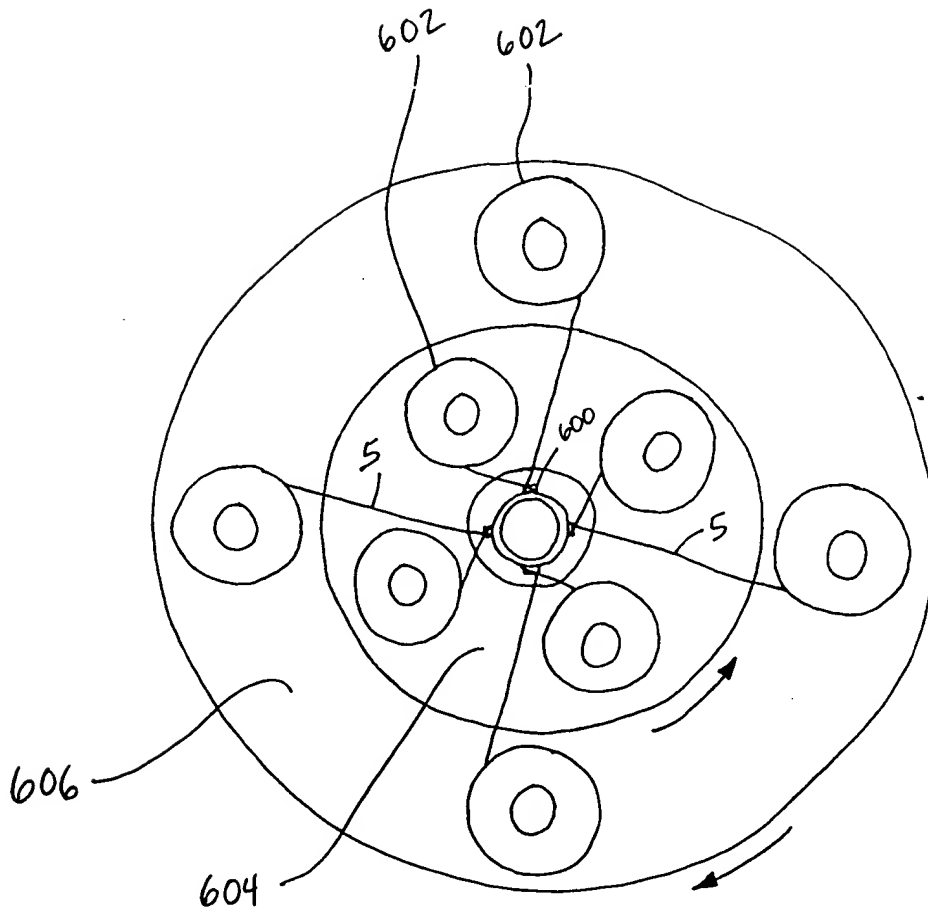


FIG. 42A

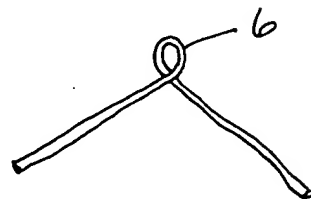


FIG. 42B

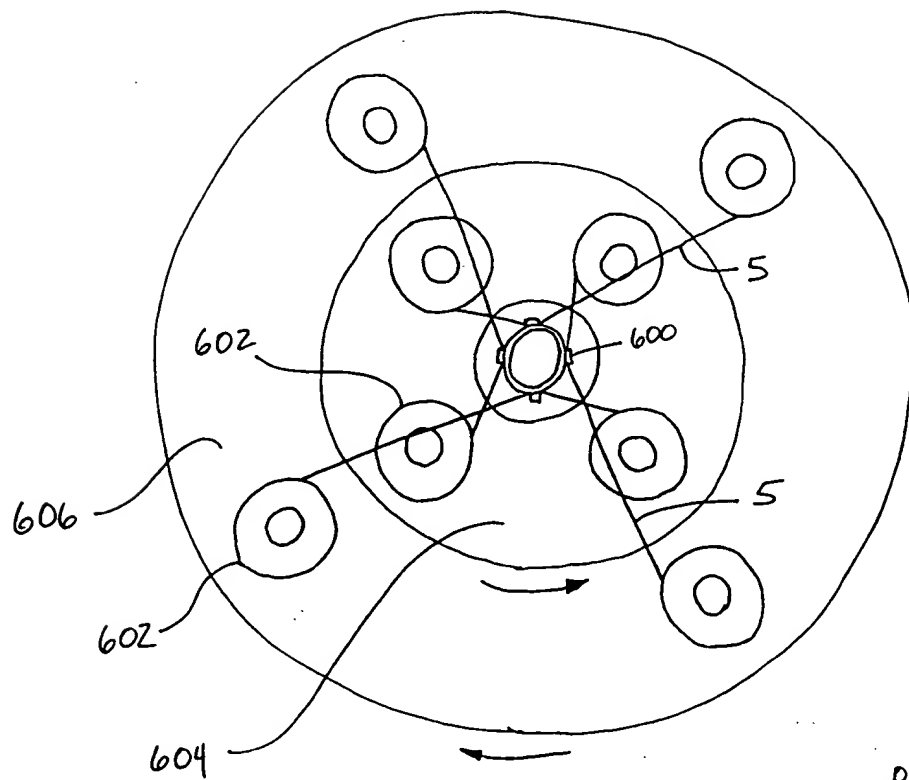


FIG. 43A

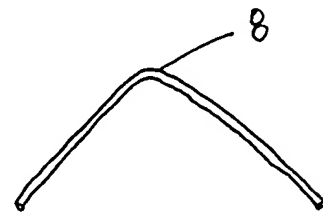


FIG. 43B

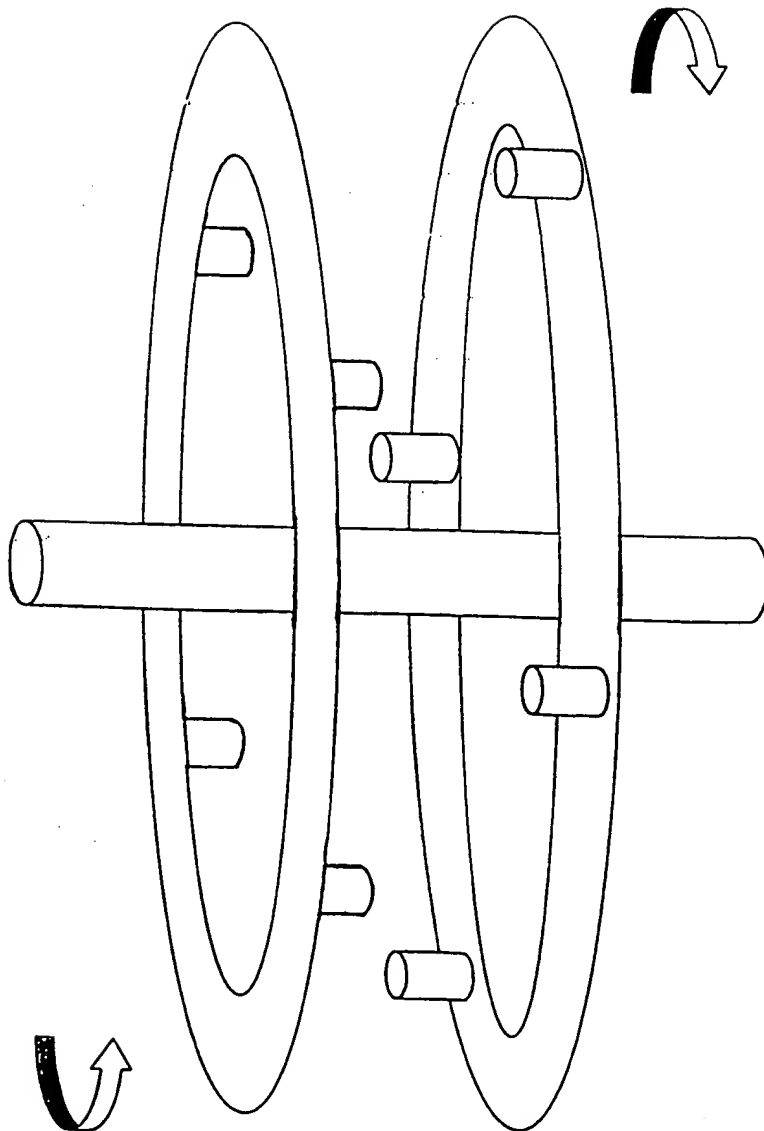


FIG. 44

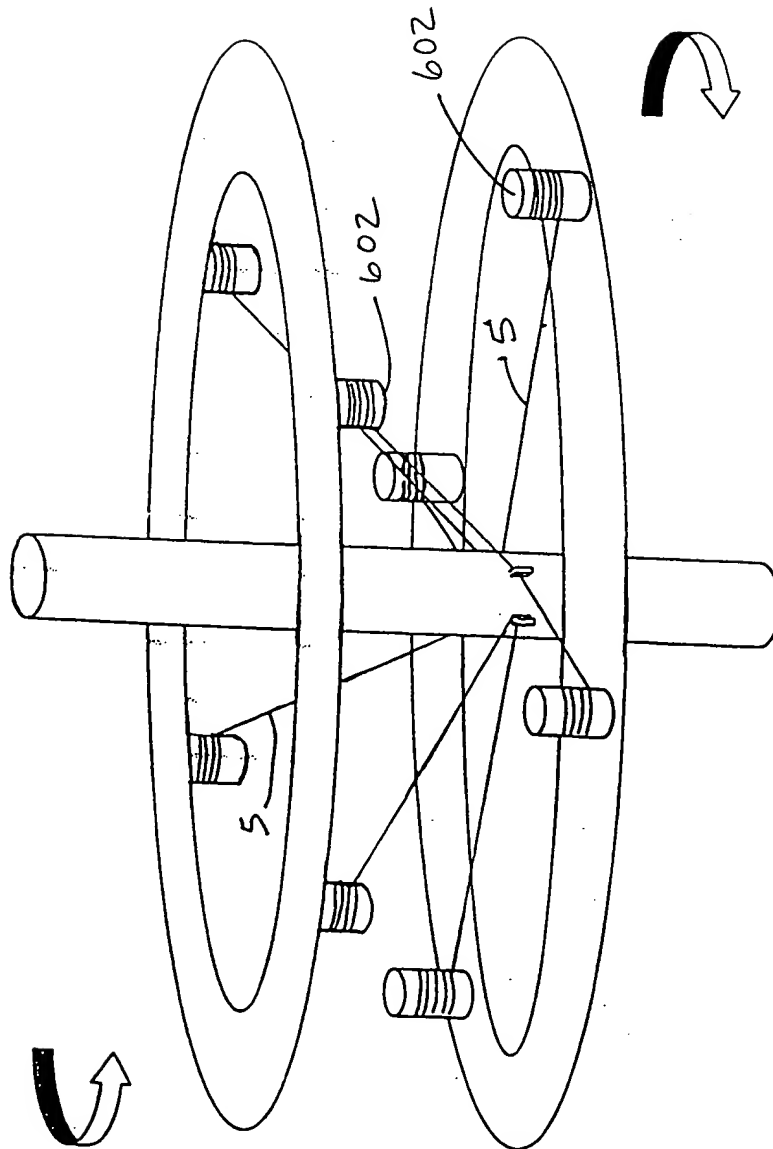
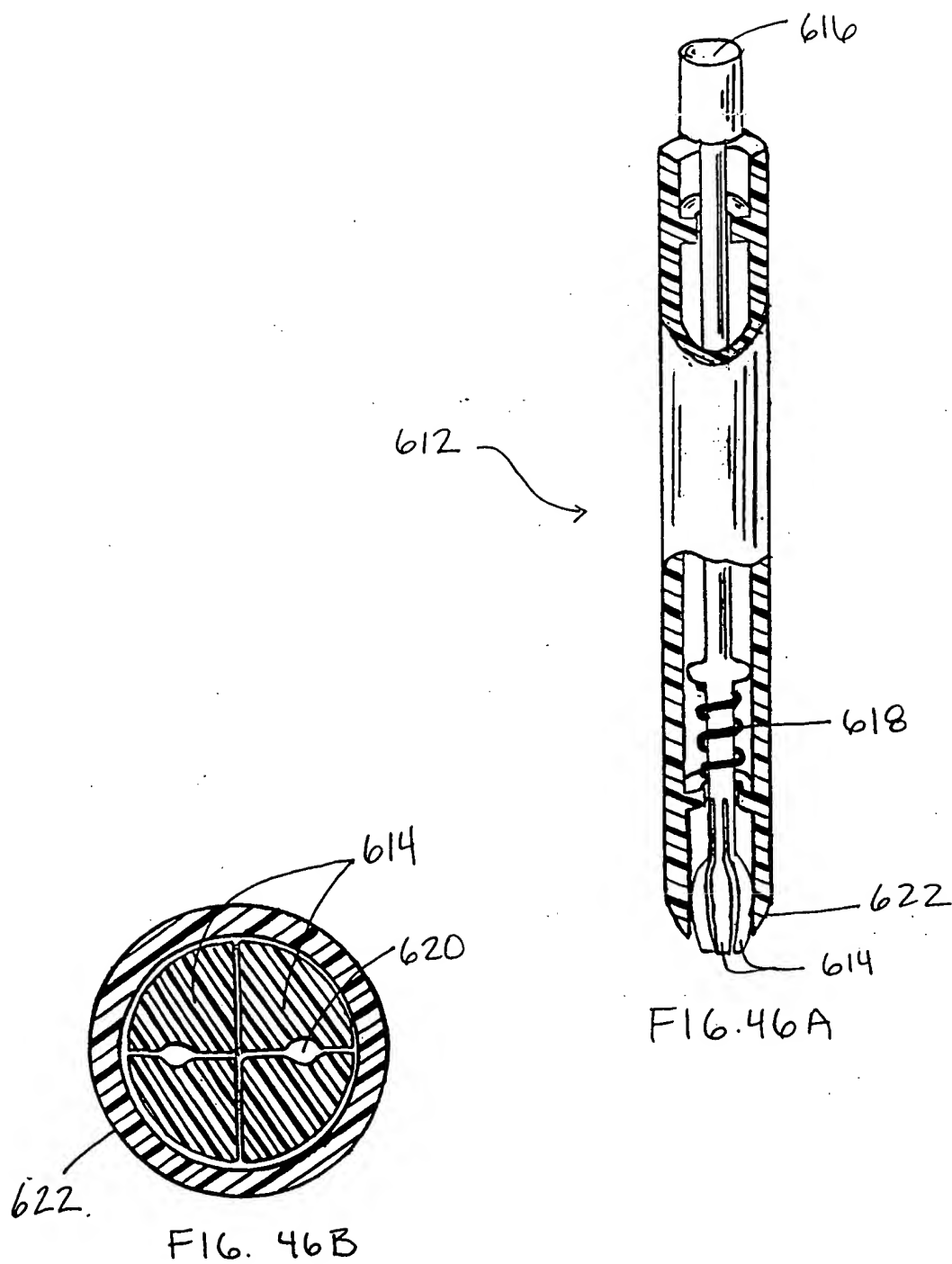


FIG. 45



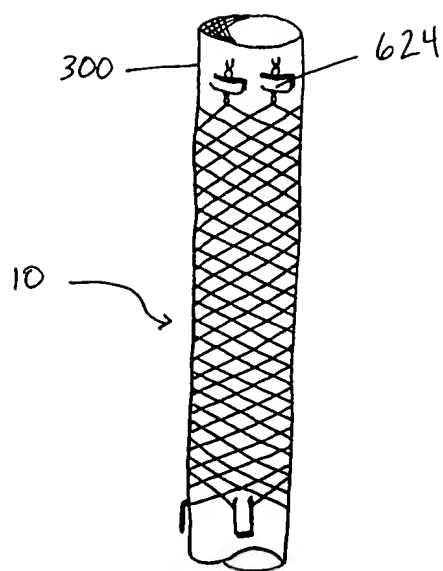


FIG. 47A

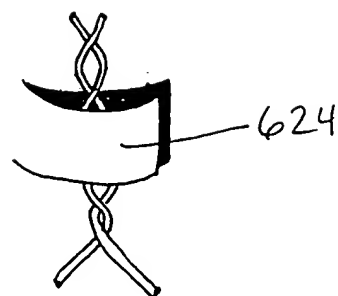


FIG. 47B



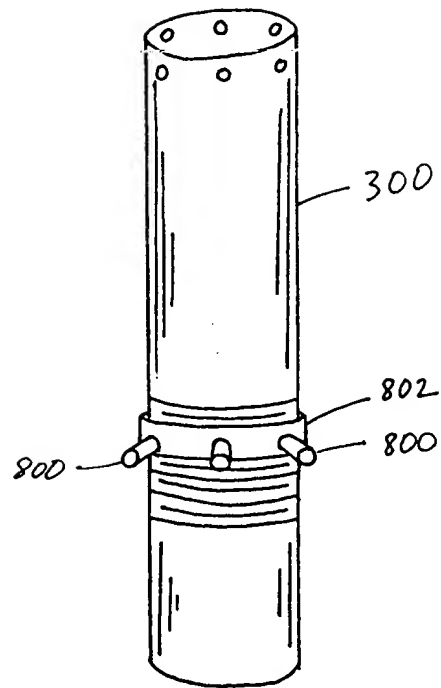


FIG. 48

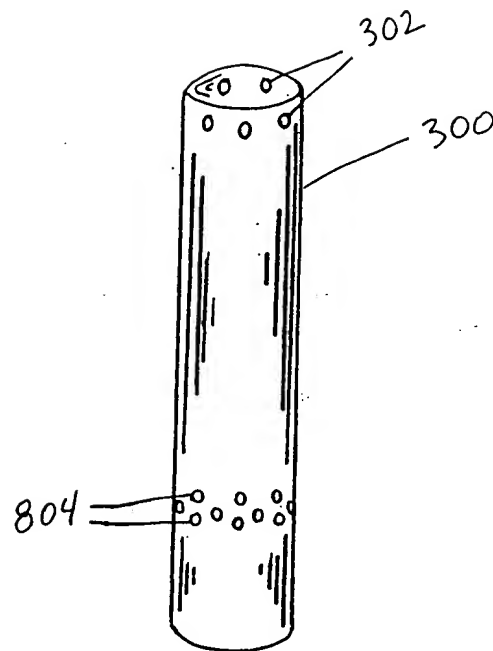
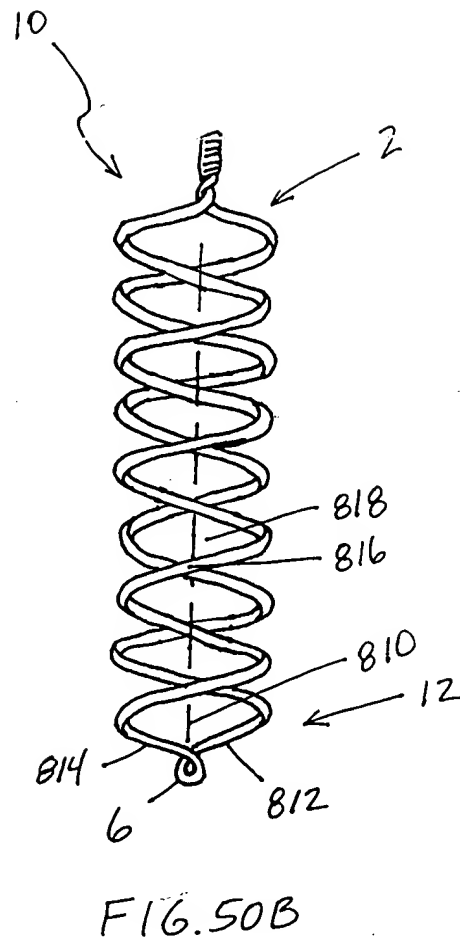
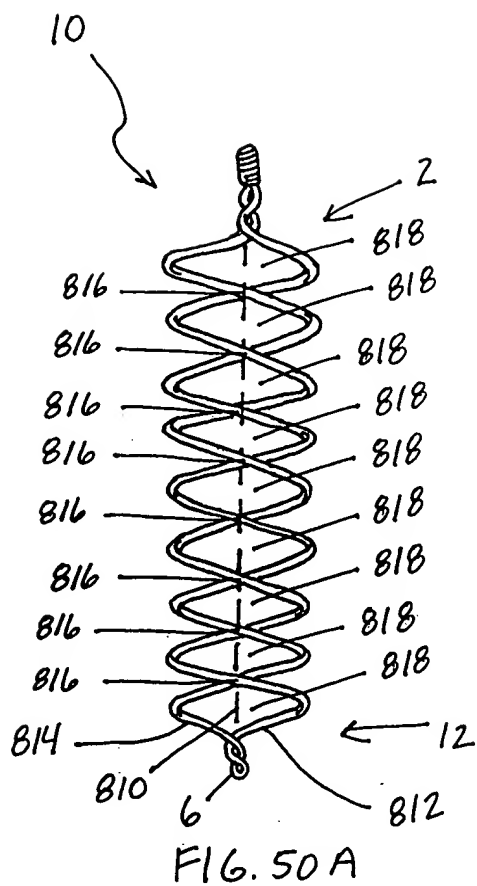


FIG. 49



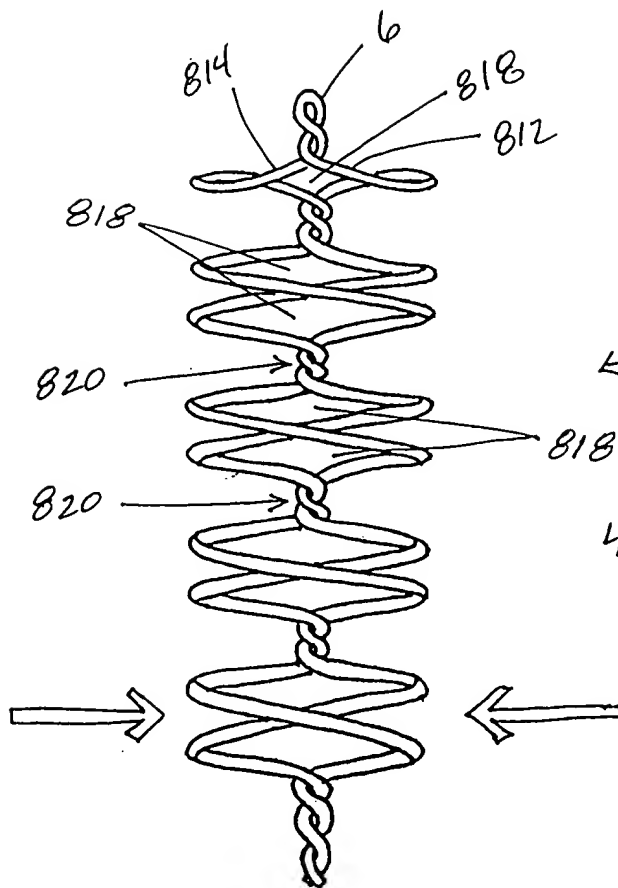


FIG. 50C

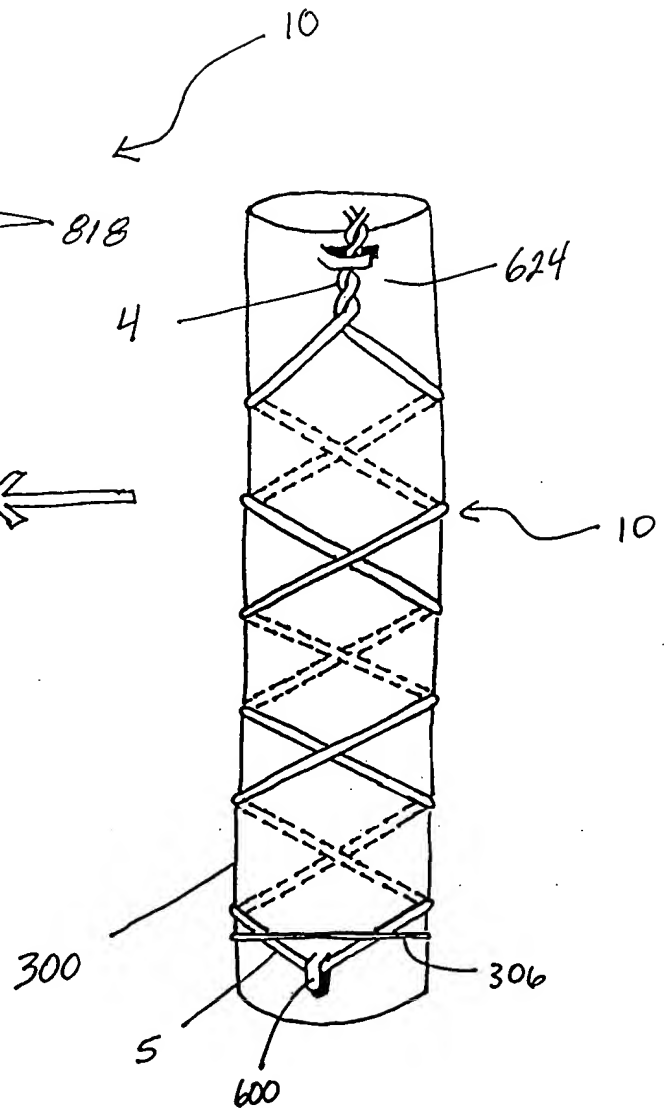


FIG. 50D

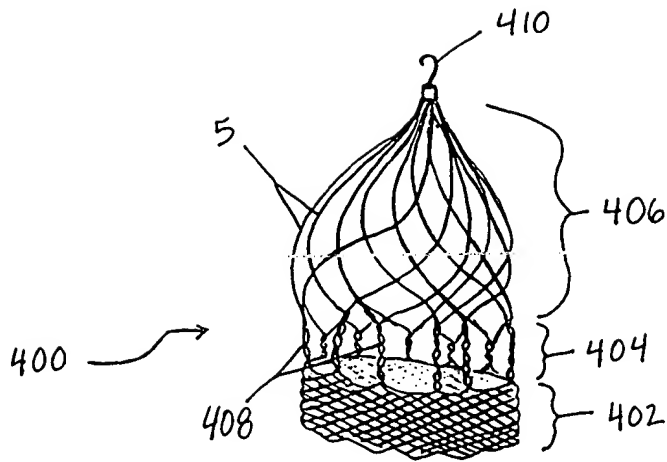


FIG. 51

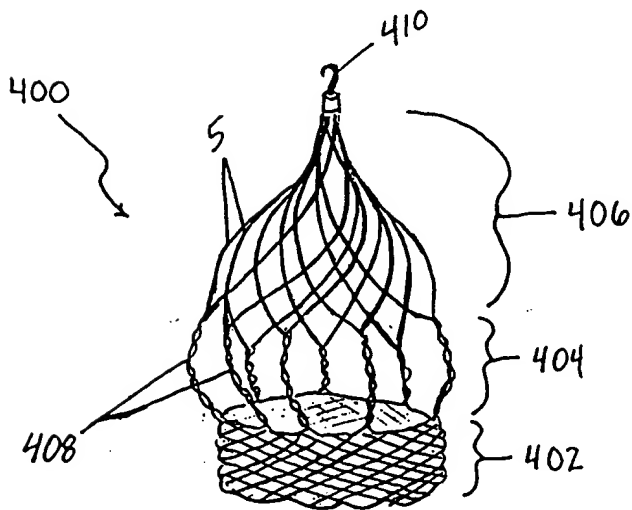


FIG. 52

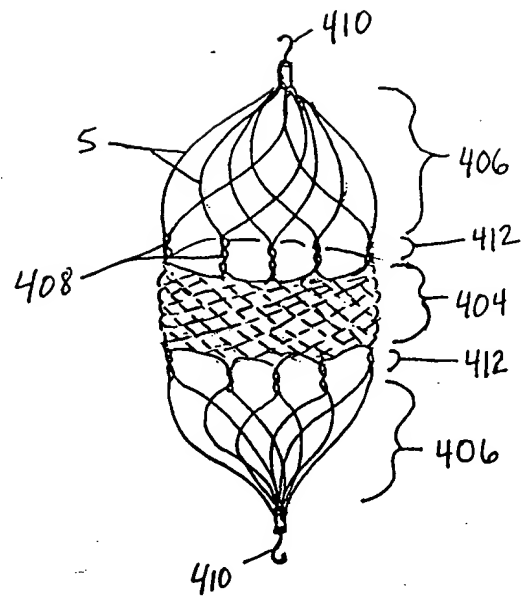


FIG. 53

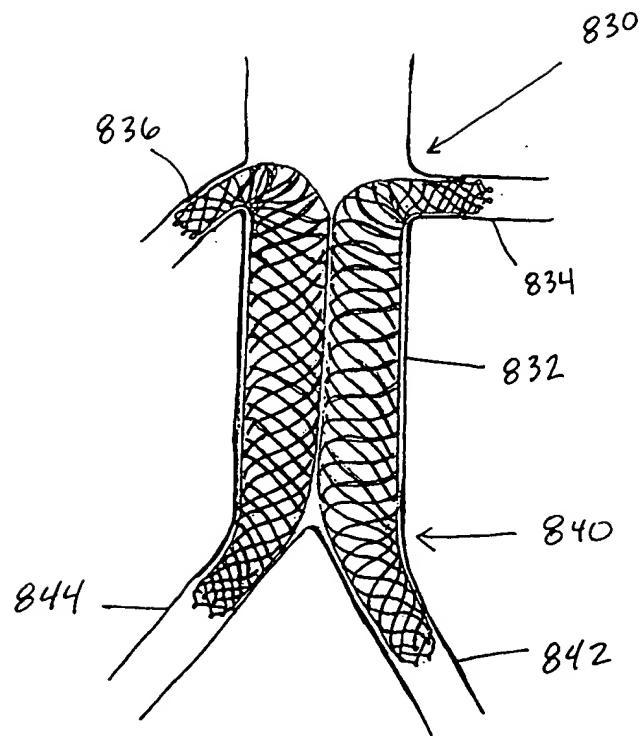


FIG. 54

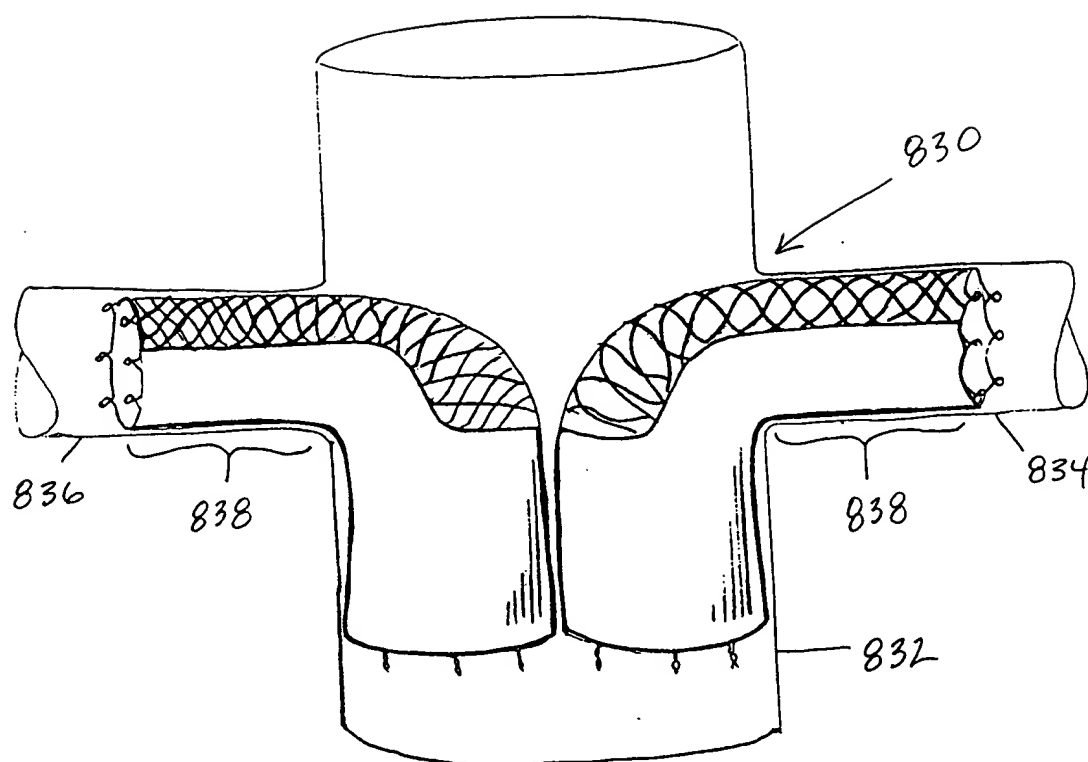


FIG. 55

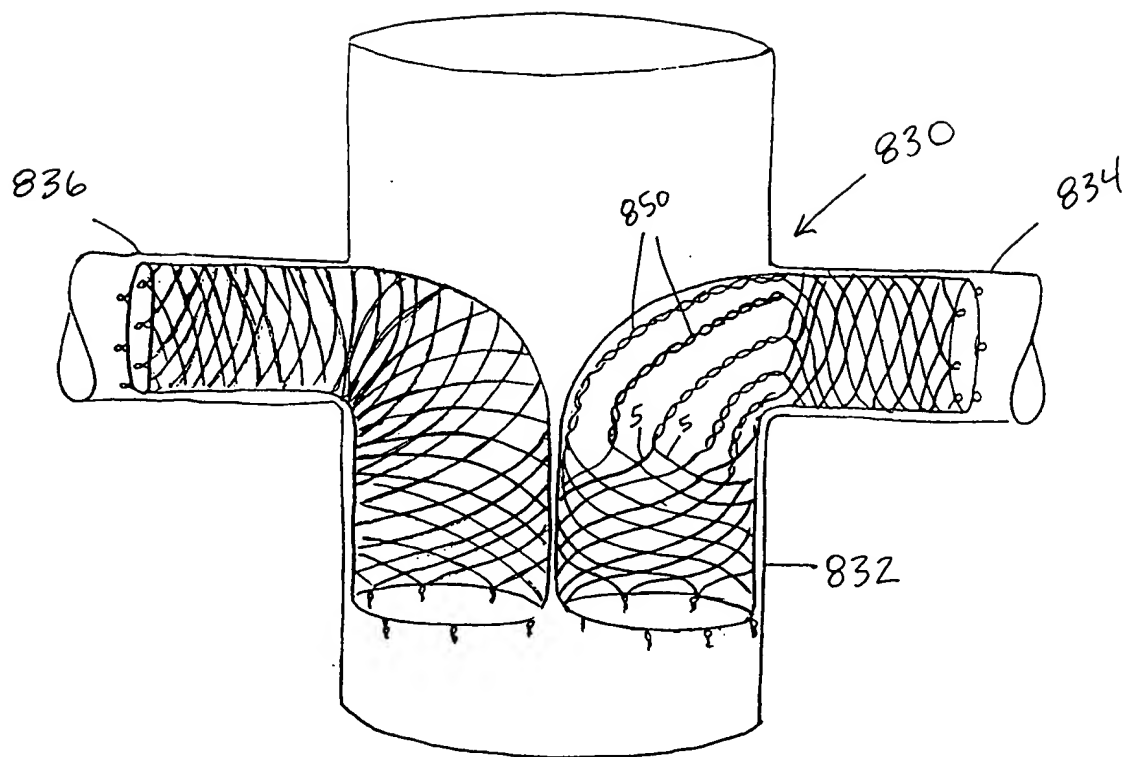


FIG. 56



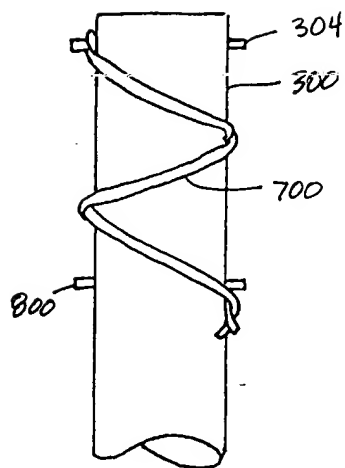


FIG. 57A

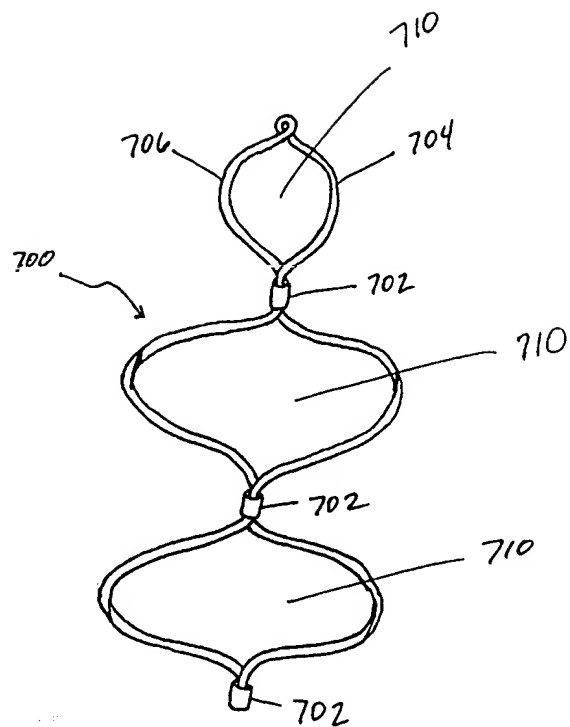


FIG. 57B

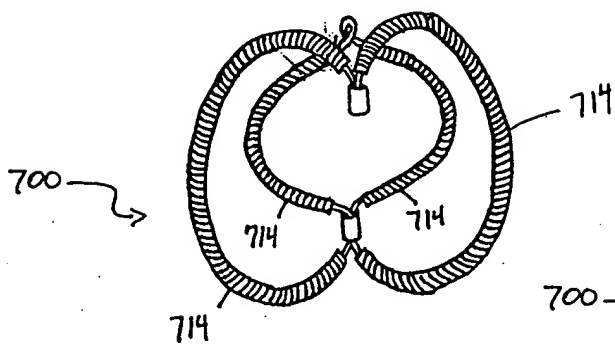


FIG. 57C

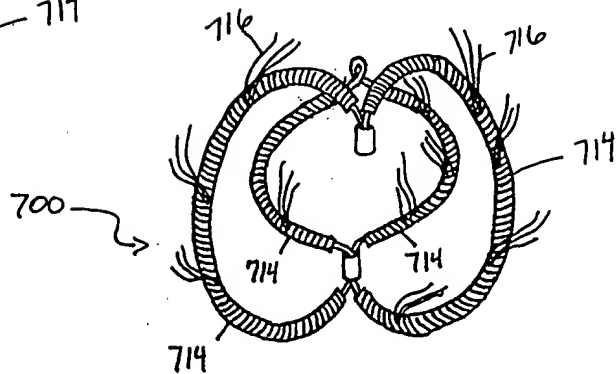


FIG. 57D

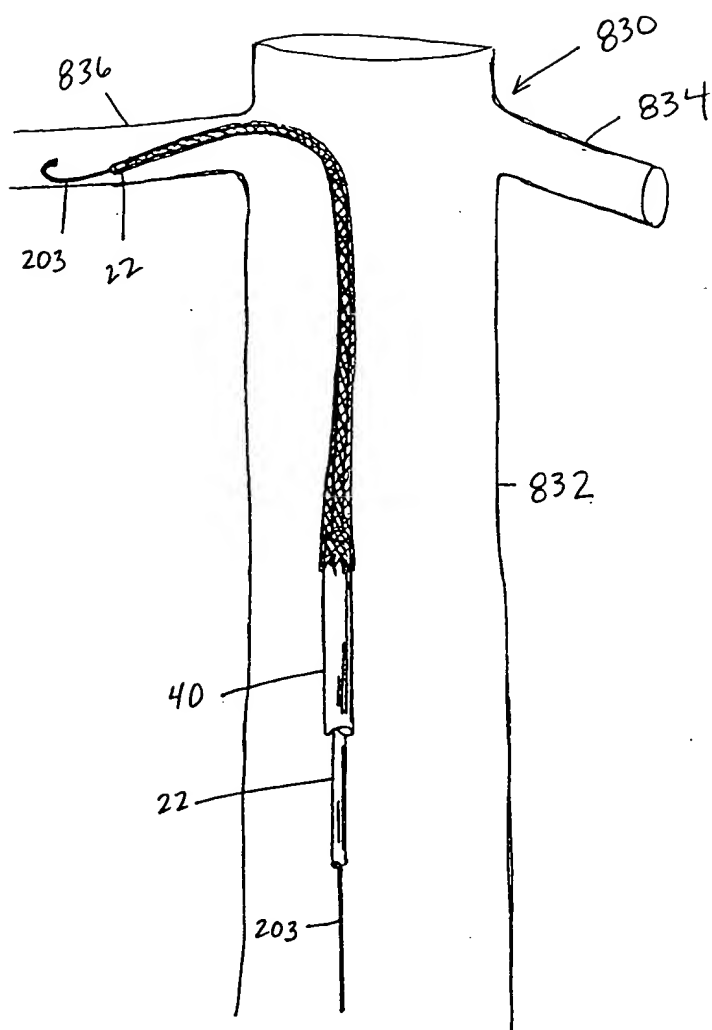


FIG. 58A

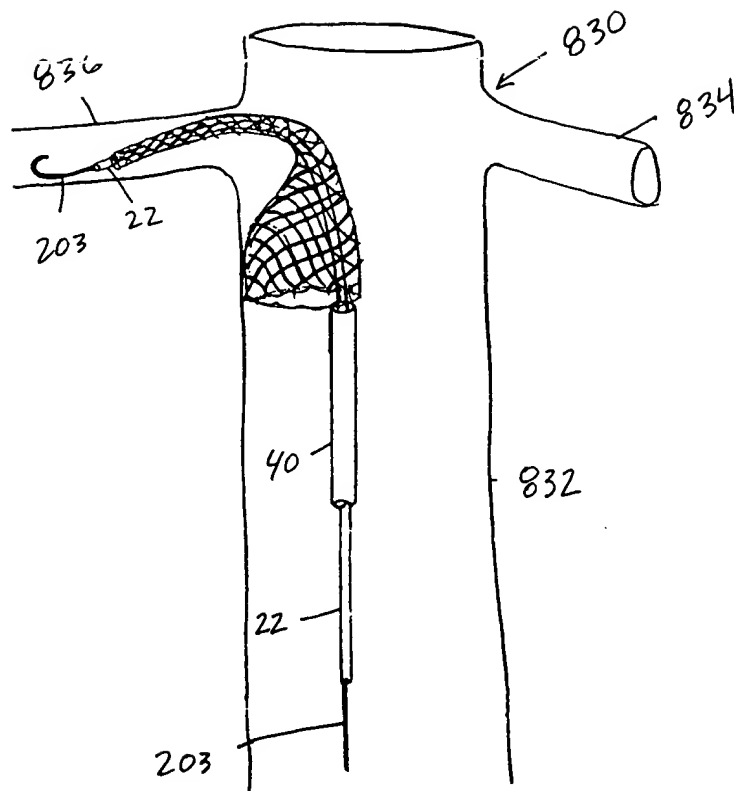


FIG. 58B

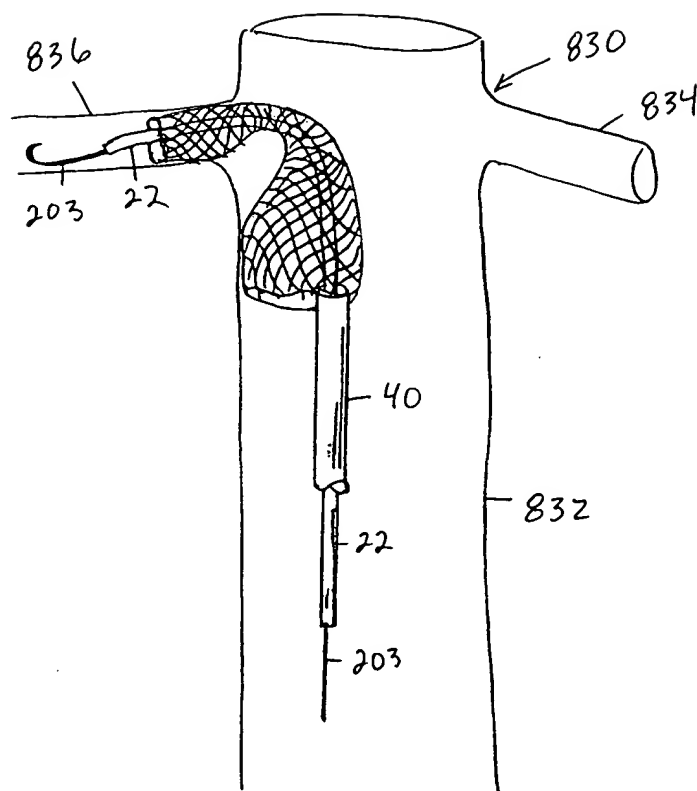


FIG. 58C

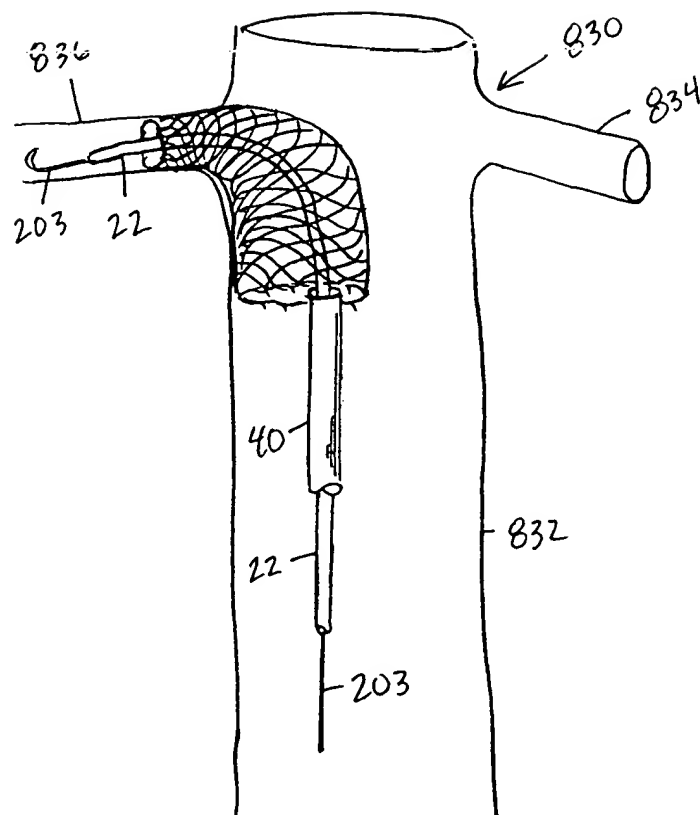
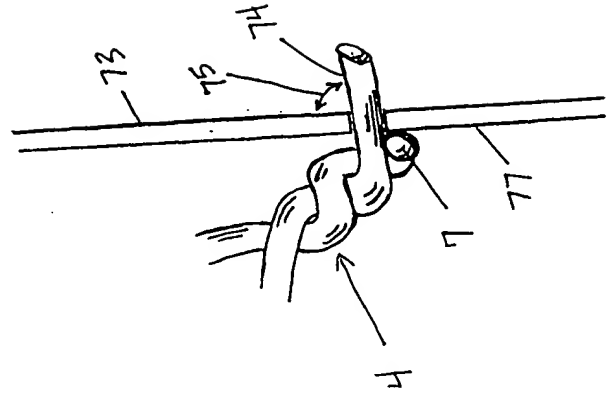
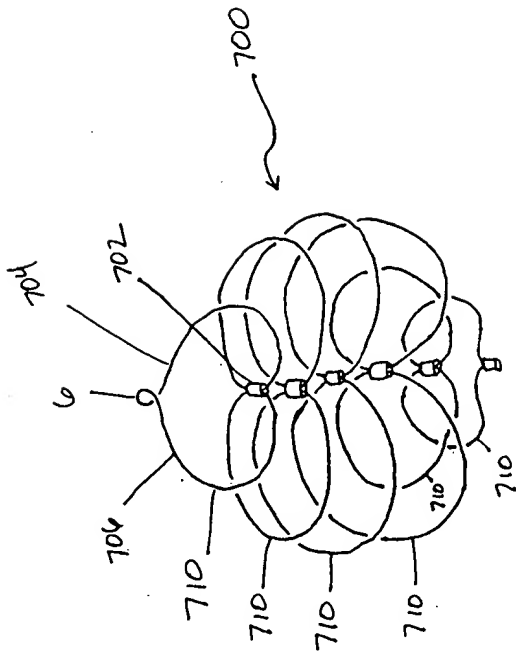


FIG. 58D



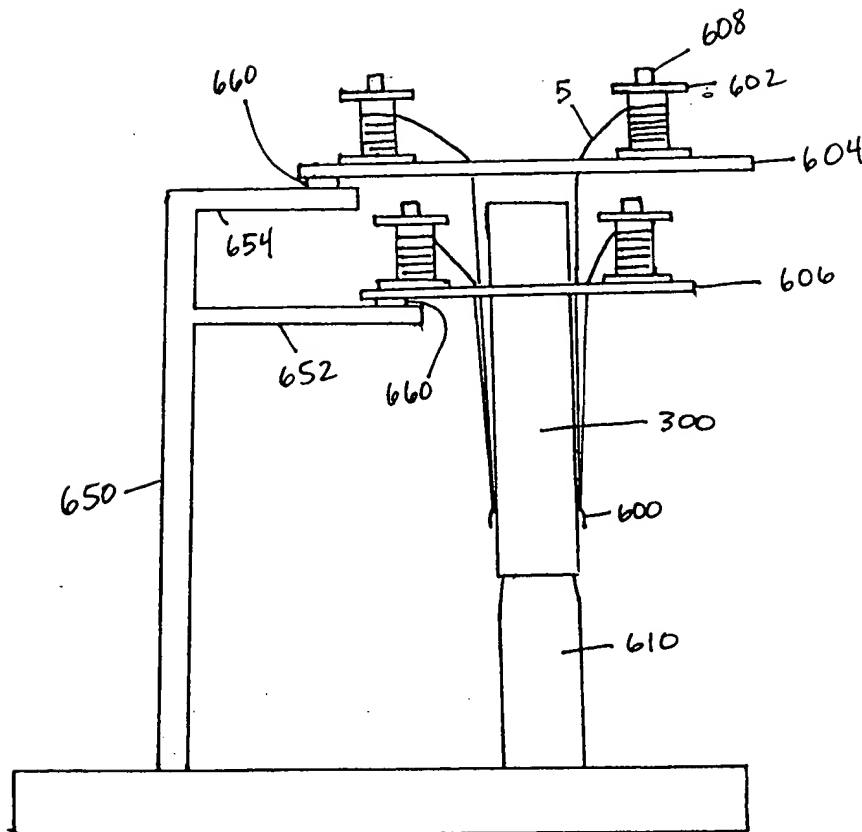


FIG. 61

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77096 (US). WRIGHT, Kenneth, C.; 1802 Haver, Houston, TX 77006-2414 (US).

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(74) Agent: GARRETT, Mark, T.; Fulbright & Jaworski, Suite 2400, 600 Congress Avenue, Austin, TX 78701 (US).

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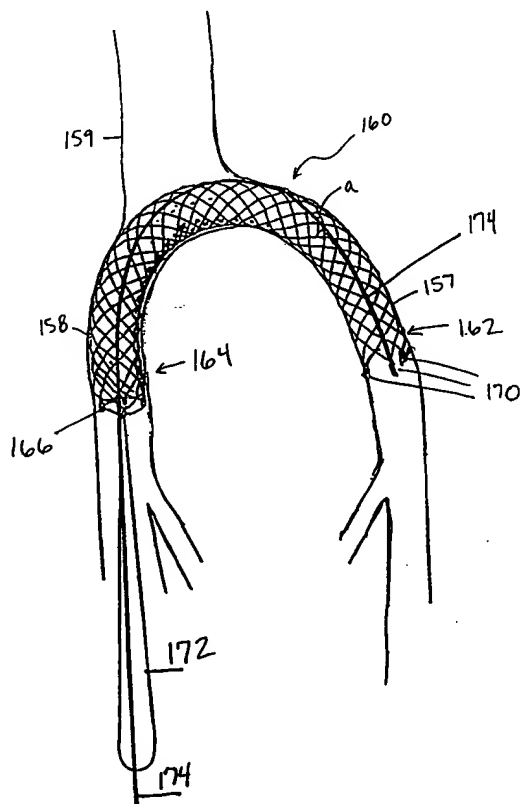
(71) Applicant: BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM [US/US]; 201 West 7th Street, Austin, TX 78701 (US).

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(72) Inventors: HYODOH, Hideki; Kawachi, Tochigi (JP). KONYA, Andras; 550 N. Braeswood #256, Houston, TX

[Continued on next page]

(54) Title: WOVEN INTRAVASCULAR DEVICES AND METHODS FOR MAKING THE SAME AND APPARATUS FOR DELIVERY OF THE SAME



(57) Abstract: Self-expandable, woven intravascular devices for use as stents (both straight and tapered), filters (both temporary and permanent) and occluders for insertion and implantation into a variety of anatomical structures. The devices may be formed from shape memory metals such as nitinol. The devices may also be formed from biodegradable materials. Delivery systems for the devices include two hollow tubes that operate coaxially. A device is secured to the tubes prior to the implantation and delivery of the device by securing one end of the device to the outside of the inner tube and by securing the other end of the device to the outside of the outer tube. The stents may be partially or completely covered by graft materials, but may also be bare. The devices may be formed from a single wire. The devices may be formed by either hand or machine weaving. The devices may be created by bending shape memory wires around tabs projecting from a template, and weaving the ends of the wires to create the body of the device such that the wires cross each other to form a plurality of angles, at least one of the angles being obtuse. The value of the obtuse angle may be increased by axially compressing the body.

WO 00/44308 A3

- With international search report.
- Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(88) Date of publication of the international search report:  
8 February 2001

# INTERNATIONAL SEARCH REPORT

Internal Application No

PCT/US 00/02569

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F2/06 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>EP 0 782 841 A (BOSTON SCIENT TECH INC) 9 July 1997 (1997-07-09)</p> <p>column 10, line 16 - line 34 column 11, line 32 - column 12, line 44 column 13, line 54 - column 14, line 2 column 18, line 56 - column 20, line 15 column 20, line 41 - line 51; figure ALL</p> <p>---</p> <p>-/--</p>	<p>1,2,5, 8-13, 17-21, 24-30, 34-36; 38-41, 44-51, 68-70</p>



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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\*A\* document member of the same patent family

Date of the actual completion of the international search

28 November 2000

Date of mailing of the international search report

07.12.2000

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# INTERNATIONAL SEARCH REPORT

Internat. Application No

PCT/US 00/02569

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 674 277 A (FREITAG LUTZ) 7 October 1997 (1997-10-07)  figures 2B,3-5 column 5, line 55 -column 6, line 30 ---	1,2,6,7, 11,12, 15,20, 21,29,32
X	WO 91 17789 A (STACK RICHARD S ;CLARK HOWARD G III (US); WALKER WILLIAM F (US)) 28 November 1991 (1991-11-28) claims 1-8 figures 2-6 ---	1,20,37
E	WO 00 09059 A (PRODESCO) 24 February 2000 (2000-02-24) figures 14-23G page 25, line 27 -page 32, line 7 page 22, line 1 -page 23, line 18 ---	51-60
P,A	WO 99 32051 A (BANAS CHRISTOPHER E ;KOWLIGI RAJAGOPAL R (US); EDWIN TARUN J (US);) 1 July 1999 (1999-07-01) figure 15 ---	51
X	WO 98 29043 A (COOK UROLOGICAL INC) 9 July 1998 (1998-07-09) figures 1-6 ---	62-64
A	page 9, line 25 -page 13, line 26 ---	65,66
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A	---	64-66
P,X	US 5 944 738 A (AFREMOV MICHAEL R ET AL) 31 August 1999 (1999-08-31) figures 1-11 claim 1 column 5, line 5 - line 47 -----	67

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 00/02569

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-50,68-70

An implantable device composed of shape memory wires woven together.

2. Claims: 51-61

A weaving system comprising a specific template.

3. Claims: 62-66

A delivery device with two tubes, a guide wire, to deliver an expandable woven body.

4. Claim : 67

An implantable occluding system.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No

PCT/US 00/02569

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Information on patent family members

Internal. Application No

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